**Cost-Effectiveness of Brentuximab Vedotin for the Treatment of Cutaneous T-cell Lymphoma in Canada**

# 1 Supplemental Appendix

## 1.1 Model Inputs

### *1.1.1* ***Efficacy***

Survival outcomes to inform the economic model were primarily based on patient-level data analyses of the ALCANZA trial. All analyses used the final ALCANZA database (July 2018) [1]. ALCANZA survival outcomes used to inform the model included OS, PFS, and time on treatment (ToT). Allogeneic SCT was considered a treatment option for a subset of eligible patients as described below. Survival outcomes for SCT were taken from conference proceedings [2]. PFS and OS for allogeneic SCT were used to inform the survival of patients post-SCT. In addition, best overall response data from ALCANZA were used to calculate the proportion of patients eligible for SCT.

In accordance with the National Institute for Health and Care Excellence (NICE) Decision Support Unit's recommendations, parametric survival models (PSMs) were fitted to allow extrapolation of immature survival outcomes [3]. Seven parametric distributions (exponential, Weibull, Gompertz, log-logistic, log-normal, generalized gamma, and gamma) for all survival outcomes except ToT were examined. The fit of each parametric distribution to the Kaplan–Meier data was assessed by visual inspection, statistical goodness of fit (based on the Akaike information criterion and the Bayesian information criterion), and clinical plausibility. For all survival outcomes, stratified survival models were selected. Equal OS between the brentuximab vedotin and MTX or BEX arms was assumed, which was supported by Canadian clinicians and survival analysis of patient-level data from ALCANZA [4, 5]. The Kaplan–Meier curves and fitted distributions for OS and PFS in the base-case analysis are shown in Figure 2.

Kaplan–Meier ToT data observed from the ALCANZA trial were complete and directly applied to the economic model, which negated the requirement for extrapolation. Overall response rate was used within the model to define the proportion of patients eligible to receive allogeneic SCT.

In the base case, a proportion of eligible pre-progression patients transitioned to allogeneic SCT at 18 weeks (6 cycles) following induction therapy with brentuximab vedotin or either MTX or BEX. Only patients who achieved a CR or PR at 18 weeks were eligible for allogeneic SCT. The clinical experts suggested that allogeneic SCT is rare in Canada, with fewer than 5% of patients currently undergoing SCT [6]. Experts agreed that brentuximab vedotin may provide a bridge to allogeneic SCT and therefore included SCT in the model; however, they did not expect the procedure to become a common practice.

We assumed 15% of the eligible responders would proceed to allogeneic SCT. Combining this assumption with response status, 3.10% of all patients treated with MTX or BEX and 9.76% of all patients treated with brentuximab vedotin would receive an allogeneic SCT. As clinical experts indicated that rates of allogeneic SCT may vary in practice, scenario analyses were conducted assuming 10% and 20% of eligible responders would proceed to allogeneic SCT.

Allogeneic SCT outcomes for patients with CTCL were derived from conference proceedings [2]. Progression-free survival data indicated a survival function synonymous with SCT, signaling that a proportion of patients were cured and remained disease free. Data on SCT were, however, immature (median OS not reached) and based on a small sample size. Built predominantly on clinical validation and taking into account statistical fit, the base-case curve fits were chosen as log-normal and Gompertz for OS and PFS outcomes, respectively [7].

### *1.1.2 Adverse events*

Grade 3 or higher treatment-related adverse events (AEs) were included in the model if they occurred in ≥5% of patients in either treatment arm of the ALCANZA trial [8]. A cut-off of ≥5% was selected, as the costs of infrequent AEs are expected to be negligible and unlikely to impact on costs and resources. The mean duration of events was pooled across treatment arms [4].

### *1.1.3 Active subsequent therapy*

In the progression health state, patients receive further lines of active subsequent therapy. Data to inform this stage were taken from the Prospective Cutaneous Lymphoma International Prognostic Index (PROCLIPI) registry study [9]. Numerous treatment options are available; thus, the PROCLIPI observational dataset was used to inform the included treatments, the proportion of patients receiving each therapy, and the duration on each therapy. The model assumed that patients treated with brentuximab vedotin or either MTX or BTX receive the same active subsequent therapies, for the same fixed duration. In addition, patients who relapse from allogeneic SCT receive the same treatments, except for total skin electron beam therapy, which is required prior to allogeneic SCT.

In the ALCANZA trial, some patients in both the brentuximab vedotin and MTX or BEX arms were treated with brentuximab vedotin after progression. Twelve brentuximab vedotin patients underwent retreatment (18.75%), and 33 patients treated with MTX or BEX had brentuximab vedotin as a crossover treatment (51.56%) [4]. For the proportion of patients receiving brentuximab vedotin after progression, the weekly drug acquisition and administration costs of brentuximab vedotin were applied for 32 weeks, the mean time on brentuximab vedotin in ALCANZA [4]. These costs were applied in the same manner as, and in addition to, the costs of other subsequent treatments. Treatment with brentuximab vedotin after relapse from SCT was not allowed. As described, active subsequent therapies were applied upon progression and continuously discounted over the duration of subsequent treatment. The remaining time spent post-progression was divided between no active treatment and end-stage disease management.

### *1.1.4 Costs*

*Drug costs*

Drug costs for brentuximab vedotin and MTX as well as for active subsequent therapies were taken from Canada-specific sources, the Association québécoise des pharmaciens propriétaires (AQPP) database [10] and the Ontario Drug Benefit Formulary (ODB) [11]. There was no publicly available price for BEX, so it was assumed to have the same cost per cycle as MTX. Additional drug costs and resource use associated specifically with BEX were therefore also

excluded. Dosing regimens of brentuximab vedotin and either MTX or BEX interventions used within the model were taken from the ALCANZA trial [12]. Relative dose intensities were also reported, allowing the model to account for dose adjustments.

For MTX, a dose range of 5 mg to 50 mg weekly was specified in the ALCANZA trial; 23.44 mg of MTX was the mean dose received and consequently a relative dose intensity value was not applicable. For brentuximab vedotin, per the product license, dose calculations for patients weighing more than 100 kg were limited to 100 kg [13]. Thus, the maximum dose per cycle was capped at 180 mg for brentuximab vedotin. BEX was dosed at 300 mg/m$^2$ per day as in the ALCANZA trial [12].

Several drugs included within the model were administered based on either body surface area or weight. In the base case, to account for drug wastage, a method-of-moments approach was used [14]. A summary of the resulting drug costs including wastage is shown in Supplemental Table 1.

**Supplemental Table 1. Summary of base-case drug costs by treatment (including wastage) for initial and subsequent therapies**

| Treatment | Cost per treatment cycle | Cost per model cycle |
|---|---|---|
| Brentuximab vedotin | $15,148.85 | $5,049.62 |
| Methotrexate | $6.33 | $6.33 |
| Bexarotene | NA | NA |
| Gemcitabine | $539.99 | $404.99 |
| CHOP | | $195.95 |
| Cyclophosphamide | $188.55 | $62.85 |
| Doxorubicin | $300.00 | $100.00 |
| Vincristine | $97.10 | $32.37 |
| Prednisone | $0.44 | $0.73 |
| Chlorambucil | $1.60 | $11.20 |
| Liposomal doxorubicin | $692.00 | $511.91 |

CHOP, cyclophosphamide, doxorubicin, vincristine, prednisone.

*Administration costs*

In addition to drug acquisition costs, the cost of drug administration was included for all active treatments. Unit costs for administering intravenous (IV) or oral therapies were identified from the literature, Job Bank Canada, and the Ontario Schedule of Fees and Benefits [15-18]. All IV therapies included a fixed cost for the physician and cost per minutes for the pharmacist, chair, and nurse time required. Oral administration was assumed to have no cost.

*SCT costs*

The cost of allogeneic SCT in Canada is $177,734 per transplant [19]. SCT relapse costs were assumed to be equivalent to the non-SCT post-progression state, both for active treatment and for end-stage palliative care, as patients who received an SCT were not worse off than those who did not.

*Adverse event costs*

Costs for AEs included in the model were taken from the Ontario Case Costing database for treatments given across inpatient and outpatient settings (Supplemental Table 2) [20]. For all AEs, 50% of patients were assumed to be treated in the outpatient setting. The overall weighted cost per weekly cycle was calculated using the cycle probability of each event weighted by the mean duration of each AE taken from ALCANZA. The total weekly AE cost was calculated as $29.66 for brentuximab vedotin and $28.74 for MTX or BEX.

AE costs were applied for the duration in which patients remained on treatment in the pre-progression state. Only AEs from initial treatment with brentuximab vedotin and MTX or BEX were included; AE costs of treatments received as subsequent therapies were not included.

**Supplemental Table 2. Unit cost per treatment setting for each adverse event**

| Adverse event | Inpatient cost [20] | Outpatient cost [20] | Notes |
|---|---|---|---|
| Peripheral sensory neuropathy | $5,808.68 | $248.73 | Peripheral sensory neuropathy – OCC code G629 Acute inpatient / ambulatory care 2017/2018 |
| Nausea | $8,587.87 | $275.53 | Nausea alone – OCC code R111 Acute inpatient/ ambulatory care 2017/2018 |
| Diarrhea | $10,576.96 | $345.79 | Diarrhea – OCC. Code K580, K591. Acute inpatient /ambulatory care, 2017/2018 |
| Fatigue | $9,498.68 | $391.84 | Malaise and fatigue – OCC code R53 Acute inpatient/ambulatory care 2017/2018 |
| Vomiting | $7,201.37 | $289.22 | Vomiting alone – OCC code R112 Acute inpatient/ ambulatory care 2017/2018 |
| Alopecia | | $161.78 | Alopecia (capitis totalis, areata unspecified, other cicatricial, cicatricial unspecified) – OCC code L630, L639, L668, L669 Acute inpatient/ambulatory care 2017/2018 |
| Pruritus | $8,090.84 | $148.35 | Pruritus (ani, scroti, vulvae, anogenital, other, unspecified) – OCC code L290-293, L298, L299 Acute inpatient/ambulatory care 2017/2018 |
| Pyrexia | $3,851.00 | $413.57 | Pyrexia of unknown origin following delivery, postpartum condition or complication – OCC code O86404 Acute inpatient/ambulatory care 2017/2018; Inpatient cost and LOS based on CIHI patient cost estimator CMG 662 (fever) |
| Decreased appetite | $0.00 | $0.00 | Assumption |
| Asthenia | $0.00 | $0.00 | Assumption |
| Dyspnea | $9,506.17 | $404.50 | Dyspnea – OCC code R060 Acute inpatient/ ambulatory care 2017/2018 |
| Maculopapular rash | $7,922.00 | $137.00 | Rash – OCC code R21 Acute inpatient/ambulatory care 2017/2018 |

| Adverse event | Inpatient cost [20] | Outpatient cost [20] | Notes |
|---|---|---|---|
| Peripheral edema | $7,397.12 | $444.60 | Generalized oedema – OCC code R601 Acute inpatient/ambulatory care 2017/2018 |
| Pruritus (generalized) | $7,145.61 | $152.31 | Pruritus unspecified – OCC code L299 Acute inpatient/ambulatory care 2017/2018 |
| Arthralgia | $7,370.00 | $295.00 | Pain in joint, multiple sites OCC code M2550 Acute inpatient/ambulatory care 2017/2018 |
| Myalgia | $6,183.83 | $272.34 | Myalgia, unspecified site – OCC code M7919 Acute inpatient/ambulatory care 2017/2018 |
| Headache | $9,327.82 | $284.84 | Headache – OCC code R51 Acute inpatient/ ambulatory care 2017/2018 |
| Anemia | $9,115.94 | $580.36 | Anemia – OCC. Code D649. Acute inpatient/ ambulatory care, 2017/2018. |
| Skin infection | $7,914.48 | $157.74 | Local infection of skin and subcutaneous tissue, unspecified – OCC code L089 Acute inpatient/ ambulatory care 2017/2018 |
| Hypertriglyceridemia | | $409.00 | Hyperglyceridemia – OCC Code E781 Acute inpatient/ambulatory care 2017/2018 |

CIHI, Canadian Institute for Health Information; CMG, case mix group; LOS, length of stay; OCC, Ontario Case Costing.

*Resource use costs*

Resource use costs associated with the routine monitoring and care of patients with CTCL were included in the model. CTCL is widely accepted as being a severe and debilitating disease driven by skin lesions and wounds, leading to progressively higher costs as the disease worsens. Based on clinical expert opinion, resource use was split into four main categories: clinical consultation and monitoring, investigations and tests, skin and wound care, and palliative and other drug treatments. Costs were sourced from available published sources and the Ontario Schedule of Benefits [21]. For each health state, a combination of published literature and clinical expert opinion was used to inform the resource use frequency.

Total end-stage management costs included end-of-life care for lymphoma patients and the CTCL-specific resource use informed by detailed end-of-life questionnaires completed by providers [5, 22]. End-stage care costs were applied for the last portion of post-progression. Generic end-of-life care costs for lymphomas were sourced from de Oliveira et al. 2016, which presents phase-specific costs for the 21 most prevalent cancer sites [22]. The terminal care phase covered the 12 months prior to death and was converted to a weekly cost that patients incurred during end-stage management.

In the base case, the model applied end-stage costs using a payoff approach including both CTCL-specific costs and generic oncology costs, which reflects the uniquely severe burden of this disease and the resource-intensive care required for patients with CTCL. Supplemental Table 3 summarizes the resource use estimates across all health states in the model.

**Supplemental Table 3. Summary resource use costs**

| Health state | Cost per weekly cycle |
|---|---|
| Pre-progression | $503.06 |
| Post-progression | $1,142.28 |
| *Post-progression – end-stage management* | |
| Generic oncology care | $1,163.51 |
| CTCL-specific care | $3,554.69 |
| Total end-stage cost | $4,718.20 |

CTCL, cutaneous T-cell lymphoma.

### *1.1.5 Utilities*

Quality-of-life data included in the model were based on the EQ-5D-3L [23] data collected within the ALCANZA trial for the ITT population. To estimate utility scores from the EQ-5D-3L data, the EQ-5D-3L responses were converted to an EQ-5D index score using the Canadian time trade-off method [24]. Any patient with at least one record of utility was included in the analysis. Health state utilities were estimated using a fixed-effects model including a random effect for patient to account for autocorrelation of patient utility scores due to multiple observations of any given patient. Utilities were derived based on a Canadian value set to populate the base-case model (Supplemental Table 4) [24].

**Supplemental Table 4. Summary of health state utilities**

| Health state | Utility | Source |
|---|---|---|
| Progression free – brentuximab vedotin | 0.77 | ALCANZA [25] |
| Progression free – methotrexate | 0.76 | |
| Progression free – bexarotene | 0.76 | |
| Health-state utility value: SCT (≤14 days post-SCT) | 0.42 | van Agthoven et al. [26] |
| Health-state utility value: SCT (14 days – 3 months post-SCT) | 0.60 | |
| Health-state utility value: SCT (>3 months post-SCT) | 0.77 | |
| Post-progression – active therapy (SCT and non-SCT) | 0.61 | ALCANZA [25] |
| End-stage management | 0.38 | Swinburn et al. [27] |

SCT, stem cell transplant.

## 1.2 Results Table: Scenario Analyses

**Supplemental Table 5. Results of scenario analyses**

| Scenario | Brentuximab vedotin | | | MTX or BEX | | | ICER |
|---|---|---|---|---|---|---|---|
| | Total costs | Total QALYs | Total LYs | Total costs | Total QALYs | Total LYs | |
| *PSA base case* | *$683,798* | *6.80* | *9.18* | *$672,693* | *6.54* | *9.03* | *$43,790* |

| Scenario | Brentuximab vedotin | | | MTX or BEX | | | ICER |
|---|---|---|---|---|---|---|---|
| | Total costs | Total QALYs | Total LYs | Total costs | Total QALYs | Total LYs | |
| Change discount rate from 1.5% to 0% | $733,289 | 7.47 | 10.09 | $733,532 | 7.12 | 9.83 | Brentuximab vedotin dominates |
| Change discount rate from 1.5% to 3% | $646,735 | 6.32 | 8.53 | $625,164 | 6.14 | 8.46 | $120,748 |
| Change discount rate from 1.5% to 5% | $596,561 | 5.69 | 7.67 | $562,707 | 5.57 | 7.66 | $274,272 |
| Time horizon set to 10 years | $676,175 | 6.31 | 8.54 | $668,462 | 6.35 | 8.77 | Brentuximab vedotin dominated |
| Time horizon set to 20 years | $680,975 | 6.60 | 8.91 | $671,244 | 6.47 | 8.93 | $76,806 |
| Time horizon set to 30 years | $684,990 | 6.80 | 9.17 | $675,790 | 6.59 | 9.09 | $44,375 |
| Log-logistic OS extrapolation, for brentuximab vedotin and MTX or BEX | $682,091 | 6.76 | 9.13 | $671,236 | 6.50 | 8.98 | $42,423 |
| Log-normal PFS extrapolation for MTX or BEX | $683,060 | 6.80 | 9.18 | $672,277 | 6.56 | 9.05 | $44,279 |
| Weibull PFS extrapolation for brentuximab vedotin | $688,346 | 6.85 | 9.26 | $675,592 | 6.60 | 9.10 | $49,443 |
| Brentuximab vedotin and MTX or BEX OS modeled separately, both log-normal extrapolations | $882,862 | 9.34 | 12.62 | $670,515 | 6.53 | 9.01 | $75,550 |
| Mean weight – 73kg | $683,360 | 6.79 | 9.17 | $671,825 | 6.54 | 9.02 | $45,709 |
| Mean weight – 83kg | $682,464 | 6.79 | 9.17 | $671,196 | 6.54 | 9.02 | $44,480 |
| Proportion of responders receiving SCT – 10% | $698,372 | 6.81 | 9.19 | $681,566 | 6.59 | 9.10 | $78,788 |
| Proportion of responders receiving SCT – 20% | $678,177 | 6.89 | 9.29 | $673,794 | 6.60 | 9.10 | $15,359 |
| Brentuximab vedotin and MTX or BEX and SCT end-stage duration – 6 months | $728,550 | 6.78 | 9.26 | $678,261 | 6.60 | 9.11 | $286,232 |
| Brentuximab vedotin and MTX or BEX and | $685,954 | 6.81 | 9.20 | $636,596 | 6.64 | 9.05 | $283,509 |

| Scenario | Brentuximab vedotin | | | MTX or BEX | | | ICER |
|---|---|---|---|---|---|---|---|
| | Total costs | Total QALYs | Total LYs | Total costs | Total QALYs | Total LYs | |
| SCT end-stage duration – 3 months | | | | | | | |
| No wastage | $662,549 | 6.81 | 9.19 | $662,696 | 6.56 | 9.04 | Brentuximab vedotin dominates |
| Wastage from mean weight and mean BSA | $679,886 | 6.81 | 9.20 | $673,621 | 6.56 | 9.05 | $25,014 |
| 3 repetitions of subsequent treatments | $701,196 | 6.81 | 9.18 | $690,695 | 6.55 | 9.03 | $41,375 |
| Alternative post-progression utility | $684,312 | 4.58 | 9.20 | $673,317 | 3.79 | 9.05 | $13,970 |

alloSCT, allogeneic stem cell transplant; BEX, bexarotene; BSA, body surface area; ICER, incremental cost-effectiveness ratio; MTX, methotrexate; LYs, life years; OS, overall survival; PFS, progression-free survival; PSA, probabilistic sensitivity analysis; QALYs, quality-adjusted life years.

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