The Cancer Drugs Fund and managed access: Real world evidence in NICE appraisals

Edwards HK[1], Landells LJ[1], Wickenden M[2], Lawton S[2], Clark P[3]

[1] *National Institute for Health and Care Excellence, Manchester, United Kingdom.* [2] *Public Health England, London, United Kingdom.* [3] *NHS England, London, United Kingdom*

Background

- In 2017 a NICE technology appraisal committee appraised brentuximab vedotin for the treatment of CD30-positive Hodgkin lymphoma. The rate of bridging from chemotherapy or brentuximab vedotin to a stem cell transplant was highly uncertain. The treatment showed the plausible potential for cost effectiveness, but it was unclear if the treatment was cost effective or not.
- The committee recommended brentuximab vedotin for use within the CDF in adults with relapsed or refractory disease after at least 2 previous therapies, if they cannot have autologous stem cell transplant or multi-agent chemotherapy.
- In April 2017 the company (Takeda), NHS England, Public Health England and NICE reached a managed access agreement. The agreement consisted of a data collection arrangement and a commercial access agreement that mitigated some of the uncertainty during data collection.

Methods

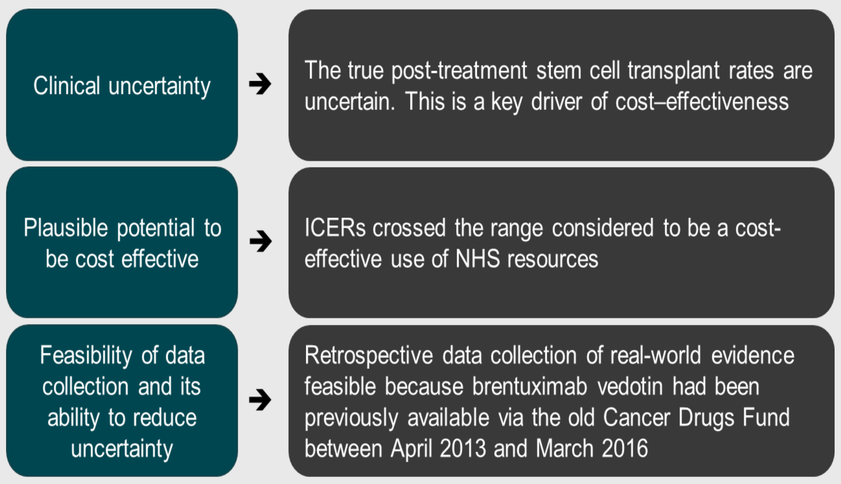
Public Health England conducted a retrospective survey of patients who had received brentuximab vedotin for Hodgkin lymphoma.

The company, NHS England, NICE and Public Heath England collaborated to design a survey for patient with Hodgkin lymphoma, to find out:

- if they had taken brentuximab vedotin
- if brentuximab vedotin had been given with the intention of bridging to a stem cell transplant
- if they had a stem cell transplant
- if they needed salvage chemotherapy to bridge to a stem cell transplant after taking brentuximab vedotin.

Patients were identified using the NHS England's prior approval system (Blueteq®). Survey administration, data collation and analysis were coordinated by Public Health England.

Figure 1: Rationale for CDF recommendation



Background to the Cancer Drugs Fund

Launched in July 2016, this new approach to appraising and funding cancer drugs in England operates via a partnership between NHS England, Public Health England and NICE. When a promising treatment is recommended by NICE for use in the Cancer Drugs Fund (CDF), data is collected to address clinical uncertainty as part of a managed access agreement.

NICE appraisal committees are able to recommend technologies for use in the CDF if all of the following apply:

- uncertainties in the evidence for clinical effectiveness mean the committee cannot recommend the technology for routine use in the NHS
- the technology has the plausible potential to be a cost effective use of NHS resources
- it is feasible to collect data that will address the uncertainties.

Results

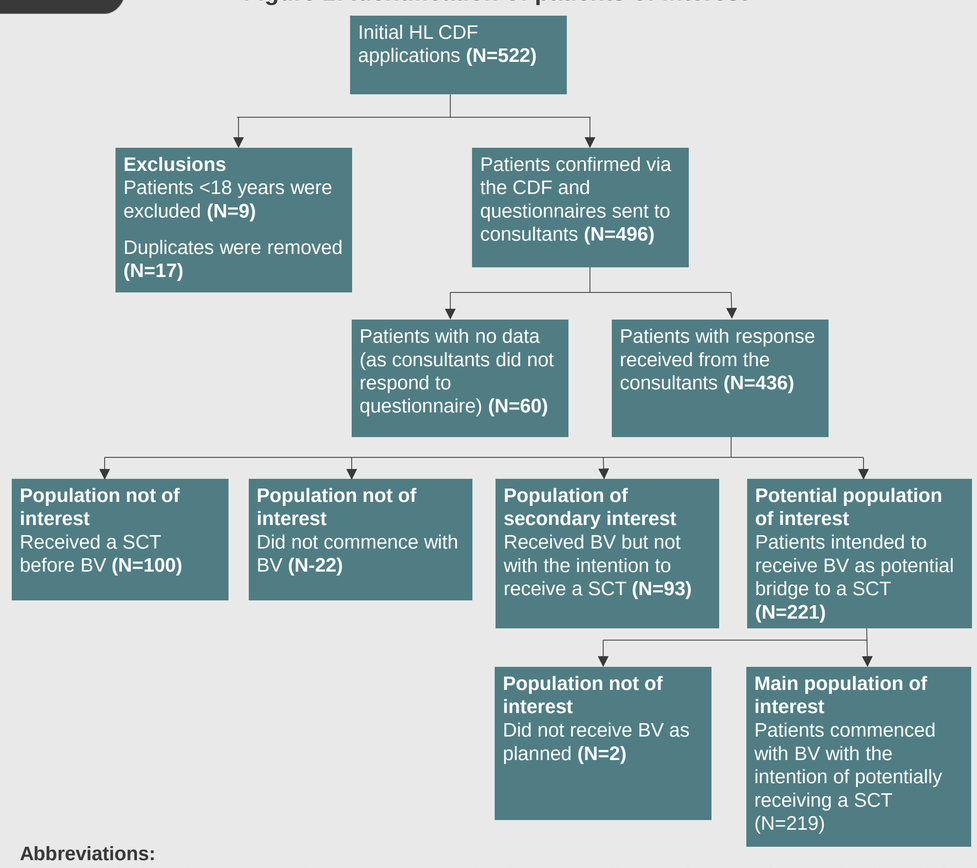
Data for patients aged 18 years or over who had a CDF application for brentuximab vedotin to treat Hodgkin lymphoma between 1 April 2013 and 31 March 2016 were extracted from NHS England's prior approval system. Questionnaires for 496 patients were sent to 223 consultants across 106 Trusts in England. Data were collected over a 6-week period, with 5 reminders sent to non-responders to maximise response rate. Of the 496 questionnaires sent out, 436 were returned to Public Health England. The results of the survey were presented in a report that was submitted to the committee and published on the NICE website[1].

Of the 522 patients identified, 219 started brentuximab vedotin as a bridge to transplant (the main population of interest). In this cohort, 78 patients had a stem cell transplant after brentuximab vedotin or after brentuximab vedotin and salvage chemotherapy. This second group includes the 78 patients who had a stem cell transplant after brentuximab vedotin and 50 additional patients who also went on to have salvage chemotherapy before having a stem cell transplant.

Following data collection the company submitted a cost-effectiveness model with the updated rate of stem cell transplant plus changes to the cost of brentuximab vedotin, the model structure, quality of life data and survival estimates.

The committee considered the new data and additional evidence provided by the company (figure 3). Because the most plausible cost-effectiveness estimate was within the range normally considered a cost-effective use of NHS resources (that is, below the range of £20,000–30,000 per quality-adjusted life year gained), the committee recommended brentuximab vedotin for routine use in this population[2].

Figure 2: Identification of patients of interest[1]



Abbreviations:
HL, Hodgkin lymphoma; CDF, Cancer Drugs Fund; SCT, stem cell transplant; BV, brentuximab vedotin

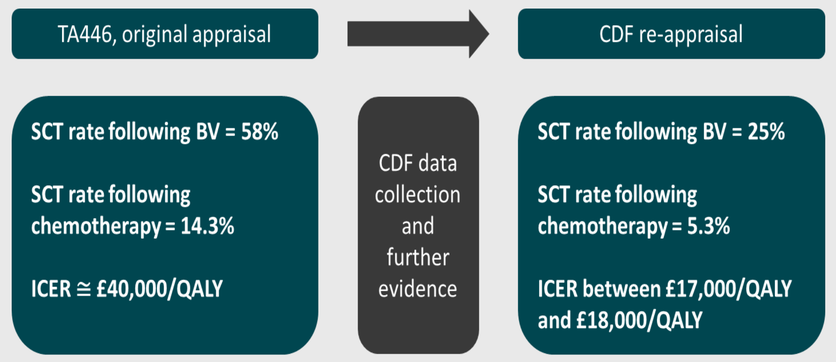
Conclusion

Key benefits of the CDF include allowing patients access to a promising drug while clinical uncertainty is resolved, and managing commercial risk to the NHS during data collection.

In May 2018 brentuximab vedotin became the first technology to be recommended for routine commissioning following a period of data collection in the CDF.

It has furthermore demonstrated the value of close collaboration between NHS England, Public Health England, NICE and pharmaceutical companies to achieve shared aims.

Figure 3: Changes to key assumptions following data collection



Abbreviations: TA446, Technology appraisal guidance 446; SCT, stem cell transplant; BV, brentuximab vedotin; ICER, incremental cost effectiveness ratio; QALY, quality-adjusted life year; CDF, Cancer Drugs Fund

Table 1: Number of people who had stem cell transplant results from the CDF data collection

Analysis	Stem cell transplant after brentuximab vedotin, n (%)	Stem cell transplant after brentuximab vedotin or brentuximab vedotin and salvage chemotherapy, n (%)
Main cohort (brentuximab with the intention of bridging to stem cell transplant)	78/219 (36%)	128/219 (58%)
Sensitivity analysis 1 (main cohort plus 60 patients without data)	78/279 (28%)	128/279 (46%)
Sensitivity analysis 2 (main cohort plus patients having brentuximab with no intention of bridging to stem cell transplant)	78/312 (25%)	128/312 (41%)
Sensitivity analysis 3 (main cohort plus all patients in sensitivity analyses 1 and 2)	78/372 (21%)	128/372 (34%)

References

1. Public Health England (2017) Brentuximab Vedotin Re-Appraisal

2. National Institute for Health and Care Excellence (2018) Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma. www.nice.org.uk/guidance/ta524

Contact: Henry Edwards
Job Title: Technical Adviser – Cancer Drugs Fund
Email: Henry.Edwards@nice.org.uk
Telephone: 0161 4134061

www.nice.org.uk