

# Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma [ID1190]

# Chair's presentation

2<sup>nd</sup> Appraisal Committee Meeting (5<sup>th</sup> February 2019)

Committee C

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**ERG: LRIG** 

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Company: Takeda

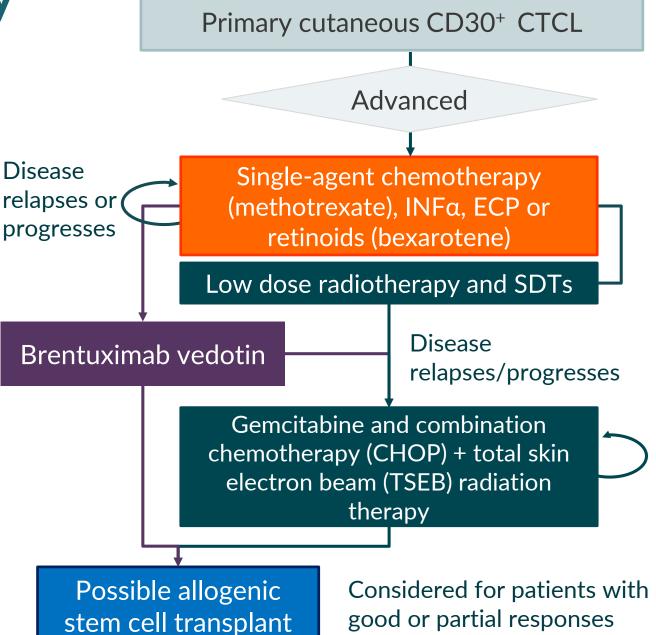
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## **Brentuximab vedotin**

Mechanism of action	Antibody–drug conjugate comprising an anti-CD30 monoclonal antibody attached by an enzyme-cleavable linker to a potent chemotherapeutic agent, monomethyl auristatin E. The antibody–drug conjugate allows for the selective targeting of CD30-expressing cancer cells
Marketing authorisation	Adult patients with CD30-positive cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy (December 2017)
Administration and dosage	<ul> <li>1.8 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks</li> <li>Patients with CTCL should have up to up to 16 cycles</li> </ul>
List price	The NHS list price of brentuximab vedotin is £2,500 per 50mg vial (ex VAT)

Appraisal consultation document treatment

pathway



# Appraisal consultation document preliminary recommendation

Brentuximab vedotin is not recommended within its marketing authorisation, for treating CD30-positive cutaneous T-cell lymphoma (CTCL) after at least 1 systemic therapy in adults.

# 1<sup>st</sup> committee meeting: key considerations

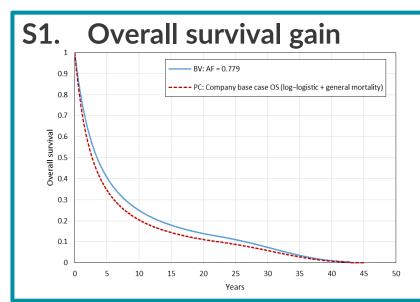
Clinical need	<ul> <li>There is an unmet need for effective treatments. Both patients and healthcare professionals would welcome potential new treatments [3.2]</li> <li>Methotrexate, bexarotene and interferon alfa are most appropriate comparators [3.4]</li> </ul>
Allogeneic stem cell transplant	<ul> <li>BV could be used as a bridge to transplant for certain patients whose disease adequately responds to treatment [3.8]</li> <li>The exact proportion who had alloSCT in clinical practice was uncertain</li> </ul>
Overall survival (OS)	<ul> <li>High degree of uncertainty about whether BV increased overall survival compared with current treatments for patients who were not able to bridge to transplant [3.9]</li> <li>The assumption of equal survival for BV and the comparators should be considered further [3.19]</li> </ul>
Health related quality of life	<ul> <li>BV's effect on health-related quality of life was unclear [3.12]</li> <li>The ERG's approach to modelling utility values (using equal values for both arms from the EQ-5D data) was suitable for decision-making [3.20]</li> </ul>
Treatment after progression	<ul> <li>Neither the company's nor the ERG's approaches to modelling treatment after disease progression are appropriate [3.19]</li> <li>The post-progression pathway for BV and the comparators should be considered further [3.19]</li> </ul>
Resource use: end-stage care	The company's base case may overestimate resource unit costs for end- stage care [3.22]

## 1st Meeting: Cost effectiveness results recap

		Total		Incremental		ICER
	Costs (£)	LYs	QALYs	Costs (£)	QALYs	ICER
Company'	s original base ca	ase				
PC		7.23		-	-	
BV		8.43				BV
						dominates
Company'	s base case (with	updated al	loSCT data)*			
PC		7.63		-	-	
BV		8.93				BV
DV		0.75				dominates
ERG's revi	ised company ba	se case				
(No alloSC	T, equal utilities	for BV and	PC, no AE disut	tility, no oral che	emotherapy o	costs)
PC		6.83		-	-	
BV		6.83				BV
DV		0.03				dominates

<sup>\*</sup> Company submitted an addendum before 1<sup>st</sup> committee meeting which included an updated base case. This was based on a later cut from the real-world study including 53 UK patients (Morris et al 2018)

## 1<sup>st</sup> meeting: ERG exploratory analyses recap

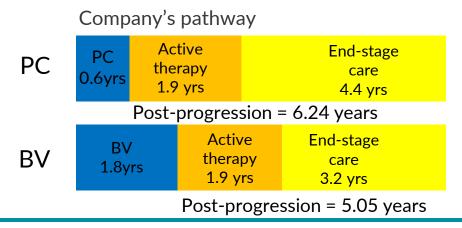


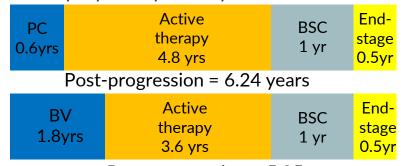
- It is not possible to say whether or not there is an OS gain associated with treatment with BV versus PC
- ERG scenario explored an OS gain equal to mean PFS gain (9.5 month gain as in the company base case when alloSCT included)
- The base case PC OS curve was used for PC
- For BV the OS curve was adjusted using an acceleration factor to generate a 9.5 month mean gain in OS

ERG's proposed pathway

## **S2.** Post progression pathway

- Company's model assumed equal survival for PC and BV and longer PFS for BV
  - → Risk of death after progression is higher for people who had BV than those who had PC
- Company assumed equal time spent on active therapy after BV or PC
  - → People who had BV spent less time and accrue less costs in high resource end-stage care





## 1st committee meeting: ERG analyses recap

## S3. Changes to resource use frequencies

ERG re-estimated some of the company's resource use estimates based on clinical advice:

- Patients in end-stage care may not be well enough to attend outpatient appointments as assumed in the company model (2.25 visits per week to 0.25 visits per week)
- Reduced proportion of patients visiting dermatologists (100 to 50) and psychologist (50 to 5)
- Palliative care and Macmillan nurses are unlikely to have capacity for several visits per week ERG reduced the frequency of visits to 0.25 for district and Macmillan nurses, palliative support and outpatient nurse visits.

ERG scenario analyses	Increme	ICER	
(no alloSCT)	Costs	QALYs	(£/QALY)
Company's base case (with updated alloSCT data)			BV Dominates
ERG's revised company base case (no alloSCT)			BV Dominates
S1: Assuming an OS gain for treatment with BV			£47,570
S2: Changes to post-progression pathway			£494,981
S3: Changes to resource use frequencies			£26,331

# 1<sup>st</sup> committee meeting: summary committee's preferences

- Committee considerations from 1st committee meeting:
  - High degree of uncertainty around all estimates
  - The model was sensitive to a number of assumptions (explored in ERG scenario analyses)
  - No analysis included all preferred assumptions:
    - Varied rates of allogeneic stem cell transplant
    - Varied number of cycles of brentuximab vedotin for patients who have allogeneic stem cell transplants
    - Equal utility values for both brentuximab vedotin and the comparators
    - No treatment-related disutilities
    - No additional oral chemotherapy costs

## **ACD:** Consultation responses

- Consultee comments from:
  - Lymphoma action
  - Royal College of Pathologists
  - Takeda UK Ltd
- Clinical expert comments
- Web comments
  - 8 x NHS Professional
    - Consultant haematologists
    - T-cell lymphoma working group
    - Skin Lymphoma clinical nurse specialist
    - Clinical oncologists

## Consultation comments: patient experiences

"Prior to starting BV I was having 24 dressings a day I was depressed.. off my food and struggled with every aspect of daily living. I am now down to only 4 dressings a day. I have put weight back on, my personality has changed my wife says I am now myself!"

"I have had 2 cycles of BV so far. It's AMAZING! I had about 80 patches on my skin some as big as 5 inches. They wept and made me extremely unhappy. They have all dried up and are healing and fading. I noticed a difference after one cycle."

"I had immediate relief. The itching stopped after the 1st infusion. By the time I had finished all cycles my lesions had all disappeared. It gave me back my confidence and life. Prior to starting the treatment, [It] made me so self-conscious. BV gave me my life back. I went on the have a transplant and am now living my life to the full Thank you!"

"My skin has gradually worsened [since diagnosis].. I have ..been subject to many different treatments... I received my first dose of BV and immediately my skin began to show significant improvement. ... I am down to 2 dressings [from 24]. It took 2 hours each day to get dressed, I had to sleep on towels each night because the skin oozed, my wife was hoovering 4 times each day because of the skin flaking and the continuous itching made my life very miserable. I now feel better generally. Others are noticing my improvement."

## **Summary of consultation comments (1)**

#### **Unmet need:**

 Advanced stages of CTCL are rare malignancies causing severe morbidity and high mortality rates and currently people have limited treatment options

#### **Clinical effectiveness:**

- More emphasis should be given to the response rates and duration of response
- Clinical effectiveness of BV is important both as a bridge to allogeneic stem cell transplant and as a palliative measure to obtain good quality of life
- Too much emphasis is placed on overall survival data, current treatment pathway aims to relieve symptoms, control local disease and improve quality of life

## Allogeneic stem cell transplant:

- Now considered for all patients with advanced stage CTCL but is only suitable for people whose disease has good or partial responses to treatment
- It is the only potentially curative treatment
- Clinical use of BV and data from the compassionate use programme supports the company's estimates of 25-30% rate of transplant

## **Summary of consultation comments (2)**

## Health related quality of life

- Advanced stage CTCL has a huge debilitating effect on people's quality of life
- People experience severe pain, constant itching and difficulty sleeping as well as unsightly, weeping lesions which have a psychological effect
- More emphasis should be given to the improvement in symptoms for people who had BV
- Clinical and patient experience of using BV suggests a significant improvement in people's health and emotional related quality of life
- Multiple case reports and patient experiences submitted in response to consultation describe severe impact of advanced CTCL on daily living and major improvement in quality of life after treatment with BV

## **Summary of consultation comments (3)**

#### Resource use

- Resource use for people without treatment likely underestimated by the committee
- People may require extensive nursing input for dressing wounds, outpatient visits, inpatient hospital stays to treat sepsis, palliative care and admission to hospices
- Managing this situation in the community is often very difficult due to lack of proper resource and expertise

## **Cancer Drugs Fund**

- Uncertainties remain in the literature
- A recommendation for BV on the CDF could help to evaluate how many people are bridged to a stem cell transplant after treatment with BV
- Access through the Cancer Drugs Fund could be considered to provide more long-term data

# Company's response to committee's preferred assumptions

The committee's preferred assumptions are "reasonable"

- Updated base case submitted to reflect the preferred assumptions
- Four key issues require further discussion:



Rates of alloSCT following treatment with BV and PC

Overall survival for patients not undergoing alloSCT

Post-progression pathway and associated resource use

# Committee preferences and company's revised analyses

Coi	Committee preference		
1	Varying rates of allogeneic stem cell transplant to reflect the uncertainty in clinical practice	<b>✓</b>	
2	Varying the number of cycles of BV for patients who have allogeneic stem cell transplants	<b>✓</b>	
3	Using equal utility values for both BV and the comparators	<b>✓</b>	
4	Removing treatment-related disutilities	<b>✓</b>	
5	Removing oral chemotherapy administration costs	<b>✓</b>	
6	Consider uncertainty around the assumptions of no overall survival gain and the post-progression pathway	<b>✓</b>	
7	Consider uncertainty around end-stage resource use costs	<b>√</b> 16	

## Company's revised base case (inc PAS)

Step changes to reflect committees preferred assumptions	ICER	NMB				
Company's base case (included alloSCT)	BV Dominates	£153,693				
Equal utility values for BV and PC	BV Dominates	£153,061				
Equal utility values BV and PC + Removing treatment-related disutilities	BV Dominates	£153,401				
Committee's preferred assumptions – the revised base case						
Equal utility values for BV and PC + Removing treatment-related disutilities + Removing additional oral chemotherapy costs	BV Dominates	£150,415				
Abbreviations: NMB, net monetary benefit (willingness-to-pay threshold of £30,000 per QALY)						

## Company's response: quality of life



### Committee consideration at 1<sup>st</sup> meeting:

- BV's effect on health-related quality of life is unclear from the trial data
- The full quality of life impact was not captured in the ALCANZA trial:
  - quality of life instruments are insensitive
  - low completion rates (57% for PC and 69% for BV)
- EQ-5D preferred by NICE and used in revised base-case
- Skindex-29 is commonly used to measure HRQL for CTCL as it is more sensitive and more accurately reflects HRQL for this disease
  - People who had BV had significantly greater symptom reduction compared with PC
  - Functional and emotional domains also showed improvement for BV but were not powered for statistical significance
- There are limitations of Skindex-29 but no tool able to fully capture HRQL
- Based on both patient and clinician feedback, BV improves the lives of patients with CTCL
- The significant improvement in response, duration of response and longer PFS almost certainly translates into quality of life benefits for patients

#### **ERG**

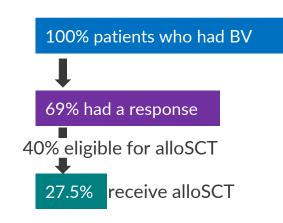
- EQ-5D may not be sensitive to skin-related diseases but should capture depression and pain described in ACD response
- No significant difference in HRQoL in Skindex-29 or EQ-5D for BV compared with PC
- Preference for using equal utility values for treatment with BV and treatment with PC

## Company's response: rates of alloSCT



Committee consideration at 1<sup>st</sup> meeting: Allogeneic stem cell transplant should be considered as part of the treatment pathway but the rate of transplant is uncertain

1. Clinical expert opinion (company's revised and original base case)



- The company assumes that 40% of responders (27.5% on BV and 7.1% on PC) will be bridged to an alloSCT
- 40% is based on eligibility for transplant considering age, co-morbidities, likelihood of matching to a donor and patient choice
- Validated as a reasonable assumption by clinical experts

#### 2. Compassionate use programme

BV in UK: 19



Eligible for SCT: 14



3 had SCT, 2 waiting\*: **5 (26.3%)** 

#### 3. ALCANZA trial data

Four of the 24 UK patients enrolled in the ALCANZA trial were bridged to alloSCT (16.7%)



<sup>\*</sup> Web comment included data from the compassionate use programme. Data indicated 2 patients are awaiting a match for a transplant



# Company's response: scenario analyses exploring the rate of alloSCT

PC	BV	ICER	NMB	
	Revised base case	BV Dominates	£150,415	
	27.5% bridged to alloSCT	DV DOMINALES	£130,413	
Revised base case	Compassionate use programme	BV Dominates	C1 / / O1 /	
7.1% bridged to	26.3% bridged to alloSCT	By Dominates	£144,816	
alloSCT	ALCANZA trial data	DV/ Dansington	COO 100	
	16.7% bridged to alloSCT	BV Dominates	£99,198	
	Revised base case	DV/ Dansington	C1/0.110	
Clinical expert	27.5% bridged to alloSCT	BV Dominates	£162,112	
submission*	Compassionate use programme	DV/ Daminatas	C15/ 51/	
5% bridged to	26.3% bridged to alloSCT	BV Dominates	£156,514	
alloSCT	ALCANZA trial data	DV/ Daminatas	C110 00E	
	16.7% bridged to alloSCT	BV Dominates	£110,895	

How should alloSCT be incorporated into the modelling?

<sup>\*</sup> Clinical expert submission suggested a lower rate of 5% of patients receiving physician's choice are bridged to alloSCT in current clinical practice

## **ERG comments:** alloSCT

ERG questions if the following assumption on the updated alloSCT data are clinically plausible?

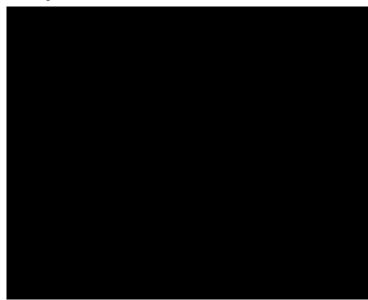
### Outcomes after relapse after alloSCT

- The company's updated model assumes outcomes are substantially worse for people whose disease progresses following alloSCT than those who did not have alloSCT
  - → Patients who relapse after transplant live on average 9.4 months compared to patients who progress following treatment with BV or PC (5.1 and 6.2yrs)

### End-stage care after relapse after alloSCT

- People whose disease relapsed following alloSCT do not receiving end-stage care
  - → Due to short mean life expectancy and requirement for time on active therapies
- Incremental costs may be higher and the QALYs lower than in the company base case

### Proportion cured and time of cure after alloSCT



- The company's model uses a single parametric curve to model PFS after alloSCT
  - → Includes both those who are cured and those who are at risk of relapse
- ERG does not consider there sufficient evidence for a cure at years for of patients
- K-M data flattens after 3yrs, but censored
   → Flat K-M implies no risk of progression or death
- ERG were not able to apply a cure fraction model
- ERG investigated cure at in which were cured

# Company's response: duration of treatment with BV before allogenic stem cell transplant

# Committee consideration at 1<sup>st</sup> meeting:

- the number of cycles of BV used prior to alloSCT varies
- would have preferred to see analyses with a range of stopping rules
- In the model the company assumed that patients who are bridged to alloSCT after treatment with BV would undergo transplant at week 18 (6 cycles) based on feedback from clinical experts
- Company acknowledge that the duration of treatment before transplant may vary and have explored scenarios where transplant takes place after 12-30 weeks

Scenario analyses duration of treatment prior to transplant	ICER	NMB
Revised base case (alloSCT after 18-weeks [6-cycles])	BV Dominates	£150,415
AlloSCT after 12-weeks (4-cycles)	BV Dominates	£152,970
AlloSCT after 24-weeks (8-cycles)	BV Dominates	£147,905
AlloSCT after 30-weeks (10-cycles)	BV Dominates	£145,304



## Company's response: overall survival

Committee consideration at 1<sup>st</sup> meeting: High degree of uncertainty about whether BV increased overall survival compared with current treatments for patients who were not able to bridge to transplant

- No robust evidence to support an OS benefit. Data from the ALCANZA trial are immature, based on a small sample size and are confounded by crossover (46%)
- Company present scenario analyses including alloSCT exploring the impact of an OS benefit:
  - a 2-month OS benefit (non-significant difference between the median OS in ALCANZA)
  - a 4-month OS benefit (mid-point between no benefit and ERG's scenario)
  - a 9.5-month OS benefit (the illustrative scenario from the ERG)
- The company do not consider a 1:1 relationship between PFS and OS benefit (ERG's analysis) clinically proven based on feedback from clinical experts who have used BV

Scenario analyses	ICER	NMB
Revised base case (no OS gain without alloSCT)	BV Dominates	£150,415
2-months OS gain for patients without an alloSCT	BV Dominates	£139,451
4-months OS gain for patients without an alloSCT	BV Dominates	£129,181
9.5-months OS gain for patients without an alloSCT	BV Dominates	£99,672

**ERG:** 9.5 months is not an upper bound. It assumes that people who had BV are modelled to have the same post-progression outcomes as people who had PC

## Company's response: post-progression pathway



Committee conclusion: Neither the company's nor the ERG's approaches to modelling treatment after disease progression are appropriate

- Assuming equal OS for BV and PC has implications on the post-progression pathway:
  - longer pre-progression period (PFS) in the BV arm → shorter post-progression period
- Company state the ERG's approach is inappropriate because:
  - No clinical rationale for different durations of active therapy in BV and PC arms
  - ERG's duration of active therapy is longer than estimated from the literature, PROCLIPI registry and clinical experience (3.6-4.8 years compared with Company's 1.9-years)
  - There are limited treatment options available for patients who have progressed
  - Best supportive care (BSC) does not exist for CTCL as current treatments cannot sustain a response
  - End-stage management for 6-months is not reflective of UK clinical practice; clinical experts suggest resource use intensive state can last for several years
- Scenario analyses of OS benefit have implications on the post-progression pathway:
  - Increasing the OS benefit associated with BV increases the length of the postprogression pathway and the duration of end-stage management

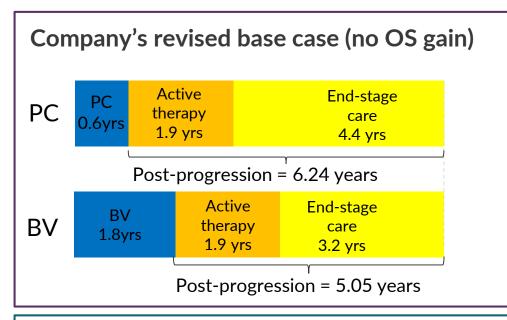
**ERG:** The company base case assumes people who had BV have worse outcomes after progression than people who had PC

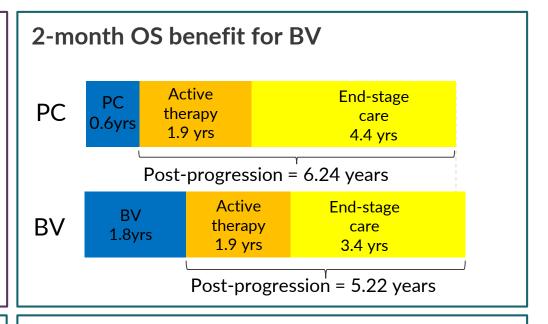
Important this is recognised when assessing the credibility of the cost-effectiveness results

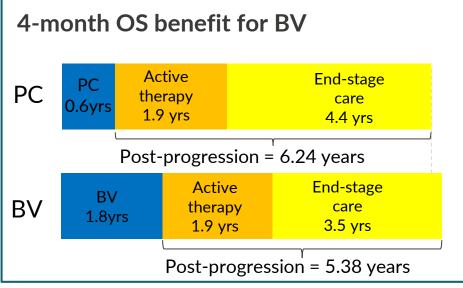
# Company's response: OS benefit and changes to the post-progression pathway

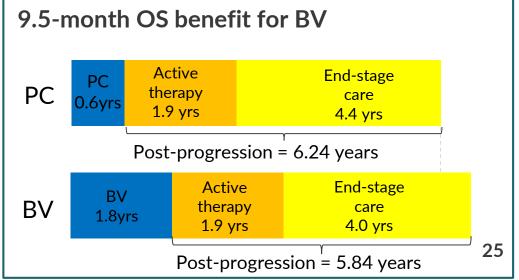


In all scenario analyses BV is more effective and less costly than PC









## Company's response: resource use



**Committee consideration at 1**<sup>st</sup> **meeting:** The company's base case may overestimate resource unit costs for end-stage care [3.22]

### Resource use frequency

- Semi-structured interviews with clinical experts, averages used in economic model
- Acknowledge that the amount of resource use per patient is a significant strain on the NHS
- Notes that advanced CTCL is a rare condition and very few patients require this support

#### Scenario considering the lower range of resource use from the clinical experts

- Higher resource use requirement than ERG scenario
- All patients will see a dermatologist, for regular appointments during end stage care
- All patients will require home based wound management (75% assumption in base case)
- 12.5% of patients see a Clinical Nurse Specialist for in-hospital dressing changes every other day, 75% require in hospital treatment every 2 weeks
- All patients receive district nurse visits (dressing changes every other day)
- Fortnightly visits from Macmillan nurse/ social services and palliative care support team

Resource use model scenarios	ICER	NMB
Company's revised base case	BV Dominates	£150,415
Company's lower range scenario	BV Dominates	£104,658
ERG's resource use scenario	£26,331	£1,226

## Company's response: resource use



	Company base case		ERG so	cenario 3	Compan	y scenario
	% patients	Frequency per week	% patients	Frequency per week	% Patients	Frequency per week
End-stage care						
Hospital outpatient						
Clinical nurse specialist	100	2.25	100	0.25	100	1.63
Dermatologist visit	100	0.17	50	0.17	100	0.17
Psychologist	50	0.25	5	0.25	5	0.25
Home visit						
District nurse visit	100	2.63	100	0.25	100	2.63
Macmillan nurse/social services	100	1	100	0.25	100	0.5
Palliative care support team	100	2	100	0.25	100	0.5
Dressings						
Mepitel dressings	25	7 (x3)	12.5	7 (x3)	12.5	7 (x3)
Mepilex large sheet dressings	25	7 (x2)	12.5	7 (x2)	12.5	7 (x2)
Mepilex heels	25	7 (x2)	12.5	7 (x2)	12.5	7 (x2)
Elasticated garments	25	1 (x1)	12.5	1 (x1)	12.5	1 (x3)
Medium Allevyn	75	7	37.5	7 (x3)	75	7
Pre-progression / Post-progression						
District nurse visit	100	2.63	100	0.25	100	0.25
Dressings – localised coverage	60	7 (x7)	37.5	7 (x7)	37.5	7 (x7)

## Company's response: cost effectiveness

Company's revised scenario analyses (all include alloSCT)		Incremental		ICER	NIMAD
		Costs	QALYs	(£/QALY)	NMB
Company	's revised base case			BV Dominates	£150,415
Rates of	Compassionate use (26.3% bridged to alloSCT)			BV Dominates	£144,816
alloSCT	ALCANZA trial data (16.7% bridged to alloSCT)			BV Dominates	£99,198
OS	2-months OS gain			BV Dominates	£139,451
benefit	4-months OS gain			BV Dominates	£129,181
from BV	9.5-months OS gain			BV Dominates	£99,672
Time on	AlloSCT after 12-weeks			BV Dominates	£152,970
BV before	AlloSCT after 24-weeks			BV Dominates	£147,905
alloSCT	AlloSCT after 30-weeks			BV Dominates	£145,304
Lower range of resource use in end stage care				BV Dominates	£104,658

## **Summary of ERG comments**

HRQoL in the ALCANZA trial	<ul> <li>EQ-5D may not be sensitive to full impact of skin-related disease but should be sensitive to depression and pain mentioned in ACD responses         <ul> <li>no significant difference in HRQoL from trial data</li> <li>EMA stated no firm conclusion could be made from the available data</li> </ul> </li> </ul>	
Overall survival without alloSCT	<ul> <li>A 9.5 month OS gain means people who did not have alloSCT and who had BV are modelled to have the same post-progression outcomes as people who had PC</li> </ul>	
Post-progression pathway	<ul> <li>The model is sensitive to changes in the post-progression pathway, it is important this is recognised when assessing the credibility of the cost- effectiveness results</li> </ul>	
AlloSCT	<ul> <li>The population in the real-world study are younger and had more advanced disease than the ALCANZA population</li> <li>The company's revised model includes several assumptions which may lack clinical plausibility:         <ul> <li>People whose disease progresses after alloSCT have substantially worse outcomes than those who relapse after treatment with BV or PC</li> <li>People whose disease relapses after alloSCT do not have end-stage care</li> <li>People who live or more years after alloSCT without relapsing are assumed to be cured ( of the alloSCT population)</li> </ul> </li> </ul>	
Resource use in end-stage care	Resource use may be overestimated by the company. The ERG's resource use scenario was based on clinical advice to the ERG  29	

## **Clinical expert opinion**

#### **AlloSCT**

- Emerging data at major centres in EU and US suggest closer to long term clinical remission after reduced intensity alloSCT (small patient numbers)
- This reflects careful selection of patients (considering response rate and comorbidities)
- Clinical experience indicates that if patients do not relapse within 12-15 months
  after transplant, they have a sustained remission

## Resource use and end-stage care

- Patients in end-stage care will require intensive skin care and supportive measures
  - Patients require multiple dressings, pain relief, psychological support and may suffer prolonged periods with significant skin infections
- High intensity end of life care is typically around 30 months but can last years
- Throughout end of life care there is little change in treatment or management of patients

## **ERG** cost effectiveness

Revisions		Incremental		ICER	NMB
		Costs	QALYs	(£/QALY)	INIVID
<b>S1</b>	9.5 OS gain after BV			BV Dominates	£99,672
<b>S2</b>	cure after alloSCT (assumes cure at years)			BV Dominates	£74,279
<b>S</b> 3	ERG resource use scenario			BV Dominates	£56,584
<b>S4</b>	ALCANZA data alloSCT rate (16.7%)			BV Dominates	£99,356

Revision	ICER (£/QALY)	NMB
[S1] and [S2]	£3,839	£23,535
[S1] and [S3]	£3,189	£33,894
[S1] and [S4]	BV Dominates	£41,118
[S2] and [S3]	£12,295	£12,885
[S2] and [S4]	BV Dominates	£63,549
[S3] and [S4]	BV Dominates	£26,384

Revision	ICER (£/QALY)	NMB
[S1], [S2] and [S3]	£40,889	-£9,805
[S1], [S2] and [S4]	£22,506	£5,311
[S1], [S3] and [S4]	£29,613	£341
[S2], [S3] and [S4]	£18,602	£5,832
[S1], [S2], [S3] and [S4]	£58,516	-£20,211

## **Equality**

There were no equality issues raised during the consultation

## **End of life**

- The company has not made a case for BV meeting the end-of-life criteria
- No comments on the committee's conclusion

## **Cancer Drugs Fund**

- The company is willing to consider the CDF for BV for this indication if it is the Committee's recommendation
- Consultees suggest a CDF recommendation could help resolve the uncertainty around alloSCT rates whilst making BV available to patients

## **Key issues**

- Should brentuximab vedotin (BV) be considered in two separate populations?
  - those who are able to have an allogeneic stem cell transplant (alloSCT) after treatment with BV
  - those not able to have an alloSCT after treatment
- What proportion of patients would receive subsequent alloSCT?
  - After treatment with BV
  - After treatment with PC
- What assumptions should be made about overall survival for people who do not have alloSCT?
  - Equal survival for people who had BV and PC
  - 2-9.5 month survival gain for people who had BV
- What assumptions should be made about the post-progression pathway?
- How does BV affect people's health related quality of life?