

APRIL 2019

Patient Assistance Program for Adcetris®

Takeda

Submitted as part of Access Accelerated

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The information in this report has been submitted by the company concerned to the Access Observatory at Boston University. The information will be updated regularly. For more information about the Observatory go to www.accessobservatory.org

The information contained in this report is in the public domain and should be cited as: Takeda, Patient Assistance Program for Adcetris® (2019), Access Observatory Boston, US 2019 (online) available from www.accessobservatory.org

Program Description

Program Overview

1 Program Name

Patient Assistance Program for Adcetris®

2 Diseases program aims to address

- Cancer: Hematological

3 Beneficiary population

- Age Group: 18 years and above
- Gender: All genders
- Special Populations: Low income

4 Countries

- Malaysia
- Egypt
- Hong-Kong
- Thailand
- Lebanon
- Mexico
- Peru
- Philippines
- Singapore
- Ukraine
- Kenya
- United Arab Emirates
- Indonesia

5 Program start date

January 19, 2017

6 Anticipated program completion date

Not specified.

7 Contact person

Susanne Weissbaecker, Susanne.Weissbaecker@takeda.com

8 Program summary

Takeda's Patient Assistance Programs (PAPs) aim to address local healthcare needs through innovative financing models. PAPs use different collaborative financing models where patients, Takeda, and at times local authorities, foundations, medical associations, charities and other parties, share the cost of treatment. The objective of this program is to allow patients to have access to and complete their entire course of our specialty medicine Adcetris® (brentuximab vedotin), for the treatment of Hodgkin's Lymphoma, even if they cannot afford to pay for it in full, through an affordability-based approach.

PAPs are implemented in countries in which Takeda is present, that have evolving healthcare systems, where a need for equitable pricing is identified, and where it is allowed by governments and the applicable laws. PAPs for Adcetris® are currently live in 13 countries (Egypt, Hong Kong, Indonesia, Kenya, Lebanon, Malaysia, Mexico, Peru, the Philippines, Singapore, Thailand, UAE and Ukraine).

Knowing that there are significant disparities in healthcare provision both within and between countries, we have adopted a personalised pricing approach rather than providing standard discounts or different tiers of pricing by GDP per capita. Delivered together with Axios International, our implementation partner, the program utilises an advanced means-based assessment tool – the Patient Financial Eligibility Tool (PFET) – that allows Axios International to determine the appropriate, individual payment scheme for each patient. In select cases, for patients with no affordability, and where appropriate and feasible, Takeda may explore other potential routes available for them to access medicines included in the PAPs. What makes the tool particularly innovative is its unique ability to segment the entire market, unlike any other patient assessment tools currently available in the market.

Axios carries out a communications campaign to inform patients and healthcare professionals about the program. Interested parties can then get in touch with Axios to request access to Adcetris® (brentuximab vedotin). Patients are also referred to the PAP by their prescribing physician. The patient and physician complete, sign and submit a single application form. Once submitted, patients undergo a confidential means-based assessment administered by Axios using PFET. Axios ensures that only eligible healthcare professionals are authorized to prescribe Adcetris® (brentuximab vedotin) in adherence to local regulations. The delivery of the specialty care medicine to the prescribing physician is managed by Axios, who further oversee the treatment. Patients enrolled in

Program Overview

8 Program summary cont.

the program receive ongoing follow-up from Axios to ensure they are adhering to their treatment plan and to their physician's recommendations.

Takeda is taking a phased approach to the rollout of our PAPs, focusing on eligible patients living in countries with evolving healthcare systems with high unmet medical needs. Our aspiration is to extend the reach of PAPs into all countries that do not have sufficiently developed healthcare systems and where there is limited reimbursement for medical expenses and where appropriate. We also aim to include other specialty medicines in our PAP, and are currently investigating the feasibility of offering a PAP for Ninlaro® for multiple myeloma.

Continuing to improve access to our specialty care products for as many patients as possible requires the integrity of our programs to be sound. We have a robust governance process in place for the consideration, approval and implementation of new programs, and a dedicated governance committee responsible for reviewing and approving the designs of our collaborative financing initiatives in consultation with other functional counterparts.

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Price Scheme

ACTIVITY	DESCRIPTION
Pricing	<p>The Patient Assistance Programs use an innovative, affordability-based method to increase access to Adcetris® in a sustainable way. They enable eligible patients to complete their course of treatment, even if they cannot afford to pay for it in full.</p> <p>The program uses a Patient Finance Eligibility Tool (PFET), independently conducted by an independent organisation.</p> <p>The PFET is a tool through which a patients ability to pay is assessed based on an individual's real financial situation. What makes the tool innovative, is its unusual ability to segment the entire market, unlike any other patient assessment tools currently available in the market.</p>
Communication	Providing information to physicians and patients who are interested in the program.

Strategy 2: Medicine Donation

ACTIVITY	DESCRIPTION
Donation	In select cases for patients with no ability to pay, and where appropriate and feasible, we may explore other potential routes available for them to access medicines included in our PAPs, such as donations or additional financial support from local medical societies, charities and NGOs.
Delivery	The delivery of the specialty care medicine to the prescribing physician is managed by Axios, who further oversee the treatment.
Communication	Providing information to physicians and patients who are interested in the program.

Companies, Partners & Stakeholders

10 Strategy by country

STRATEGY	COUNTRY
Price Scheme	[No response provided.]
Medicine Donation	[No response provided.]

11 Company roles

COMPANY	ROLE
Takeda	Planning, monitoring, and evaluating the program. Funding the program. Supplying a portion of the medicines used in a course of treatment free of charge.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
Axios International	Handles day-to-day management of the program, patient financial eligibility assessment, promotion of the program, answering questions from and providing information to physicians and patients, and delivery and management of free-of-charge medicines. https://axiosint.com/	Private

Companies, Partners & Stakeholders

13 Funding and implementing partners by country

PARTNER	COUNTRY
Axios International	Malaysia, Egypt, Hong-Kong, Thailand, Lebanon, Mexico, Peru, Philippines, Singapore, Ukraine, Kenya, United Arab Emirates, Indonesia.

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Government	Takeda works closely with national and local governments on the design of programs, to ensure that they are fully aligned with local regulations for example in terms of prescription, health professional licensing, and marketing authorization for the product.	Infrastructure: No Human Resources: No Funding: No Monitoring or Oversight: No Other resource: No

Local Context, Equity & Sustainability

15 Local health needs addressed by program

Unmet need

- Patient Assistance Programs are tailored to address local needs and use different collaborative models where patients, Takeda, and at times local authorities, foundations, medical associations, charities and other parties, share the cost of treatment.
- In some developed healthcare markets there may be a gap between a patient receiving treatment and the reimbursement of medical expenses. In order to address this gap, we have introduced the PAPS as bridge funding to ensure patients can access treatment when they need it.
- Before the launch of Adcetris®, there were no treatment options for patients with relapsed and refractory Hodgkin's lymphoma (RR HL) or relapsed and refractory systemic anaplastic large cell lymphoma (RR sALCL) in many developing markets.

Approach and implementation, including consideration for local health needs and challenges, policies, practices and laws

- PAPS use an innovative, affordability-based approach to improve access to specialty medicines like Adcetris in a sustainable way in areas where there are high, unmet medical needs.
 - We utilize the Patient Financial Eligibility Tool (PFET) independently conducted by Axios International.
 - The PFET is a tool through which a patient's ability to pay is assessed based on an individual's real financial situation. What makes the tool particularly innovative is its unusual ability to segment the entire market, unlike any other patient assessment tools currently available in the market.
- They are implemented in countries in which Takeda is present, that have evolving healthcare systems, where a need for equitable pricing is identified, and where it is allowed by governments and the applicable laws.

a How needs were assessed

[No response provided.]

b Formal needs assessment conducted

No.

16 Social inequity addressed

Yes, the objective of the program is to allow patients to have access to and complete their entire course of treatment, even if they cannot afford to pay for it in full, through an affordability-based approach. In some developed healthcare markets there may be a gap between a patient receiving treatment and the reimbursement of medical expenses. In order to address this gap, we have introduced PAPS as a bridge funding to ensure patients can access treatment when they need it.

This program is about making Adcetris® (brentuximab vedotin), for the treatment of Hodgkin Lymphoma accessible.

17 Local policies, practices, and laws considered during program design

POLICY, PRACTICE, LAW	APPLICABLE TO PROGRAM	DESCRIPTION OF HOW IT WAS TAKEN INTO CONSIDERATION
National regulations	Yes	Takeda works closely with national and local governments on the design of programs, to ensure that they are fully aligned with local regulations for example in terms of prescription, health professional licensing, and market authorisation of the product.
Procurement procedures	—	—
Standard treatment guide-lines	Yes	<ul style="list-style-type: none"> Patients are referred to the PAP by their prescribing physician. The patient and physician complete, sign and submit a single application form. Once submitted, patients undergo a confidential means-based assessment using a validated tool designed and administered by an independent, third-party organisation - Axios International. The results of the assessment are used to develop a payment plan that details how many vials of treatment will be covered by Takeda and other parties to ensure that the patient is able to complete the full treatment cycle. Patients enrolled in the program receive ongoing follow-up from Axios to ensure they are adhering to their treatment plan and to their physician's recommendations. The consideration, approval and implementation of PAPs is done through a robust governance process with supporting documentation.
Quality and safety requirements	Yes	Takeda works closely with national and local governments on the design of programs to ensure that they are fully aligned with local regulations for example in terms of prescription, health professional licensing, and market authorisation of the product.
Remuneration scales and hiring practices	—	—
Other, please specify	Yes	PAPs use an innovative, affordability-based approach to improve access to specialty medicines like Adcetris® in a sustainable way in areas where there are high, unmet medical needs.

18 How diversion of resources from other public health priorities are avoided

This is a Takeda led initiative, which is delivered with the support of an independent organisation and therefore does not divert resources away from other public health priorities.

19 Program provides health technologies (medical devices, medicines, and vaccines)

Yes.

TYPE	COMMERCIAL NAME	INTERNATIONAL NON-PROPRIETARY NAME AND/OR INN
Medicine	Adcetris	Brentuximab Vedotin

20 Health technology(ies) are part of local standard treatment guidelines

No. This program is about improving access to our innovative speciality medicines for patients suffering from Hodgkin Lymphoma. Before the launch of Adcetris®, there were no treatment options for patients with relapsed and refractory Hodgkin's Lymphoma (RR HL) or relapsed and refractory systematic anaplastic large cell lymphoma (RR sALCL) in many developing markets.

21 Health technologies are covered by local health insurance schemes

No. In some markets it is covered, and other markets not.

22 Program provides medicines listed on the National Essential Medicines List

No. This program is about improving access to our innovative speciality medicines for patients suffering from Hodgkin Lymphoma. Before the launch of Adcetris®, there were no treatment options for patients with relapsed and refractory Hodgkin's Lymphoma (RR HL) or relapsed and refractory systematic anaplastic large cell lymphoma (RR sALCL) in many developing markets.

23 Sustainability plan

- Sustainability is a key element to this program, and is indeed what it is geared around.
- Our targeted, affordability-based approach allows Takeda to optimize both the number of patients that can access treatment and the related treatment benefits in a sustainable way, by enabling patients to complete their full course of treatment, even they cannot afford to pay for it in full.
- We believe this provides more sustainable access to medicines for eligible patients than untargeted price reductions or donations.
- To ensure program sustainability, enrolled patients will be asked to pay for what they can afford.
- In select cases for patients with no ability to pay, and where appropriate and feasible, we may also explore other potential routes available for them to access medicines included in our PAPs, such as donations or additional financial support from local medical societies, charities and NGOs.
- The performance of our PAPs are monitored and reported on continuously – with KPIs integrated into both the design and implementation of each.
- We produce monthly country level reports to monitor the performance of each PAP to ensure that we can adjust and adapt them according to need and performance.

Additional Program Information

24 Additional program information

[No response provided.]

a Potential conflict of interest discussed with government entity

Yes. In certain countries we have done so,
and others not.

25 Access Accelerated Initiative participant

Yes.

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Yes.

Program Indicators

PROGRAM NAME

Patient Assistance Program for Adcetris

27 List of indicator data to be reported into Access Observatory database

INDICATOR	TYPE	STRATEGY	2017	2018
1 Staff time	Input	All Program Strategies	---	---
2 Number of patients reached with pricing scheme	Output	Price Scheme	---	---
3 Patients on appropriate treatment	Outcome	Price Scheme	---	---

INDICATOR **Staff time**

STRATEGY ALL PROGRAM STRATEGIES

ITEM	DESCRIPTION
Definition	The ratio of the total number of paid hours during a year by the number of working hours in that period. This indicator excludes the time of volunteers or staff time for external partners.
Method of measurement	<p>The ratio is also called Full Time Equivalent (FTE).</p> <p>CALCULATION</p> $\frac{\text{Sum of the number of paid hours per year}}{\text{Total number of working hours per year}}$
28 Data source	Routine Program Data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company	The staff from Takeda working on this program track the number of hours spent working on the program.	Once per year
31 Data processing	Company	Staff who are in charge of the program will use the data of staff time spent on the program to calculate the Full Time Equivalent (the ratio of the total number of paid hours during a year by the number of working hours in that period) and report it to the Access to Medicines office by email. The Access to Medicines office will review the data as necessary.	Once per year
32 Data validation		Further validation of internal human resources records in relation to staff time is not performed.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018
1 Staff time	---	---

Comments: N/A

ITEM	DESCRIPTION
Definition	Number of individuals that received medicines included in the price scheme.
Method of measurement	Counting the number of individuals that received medicines included in the price scheme. CALCULATION Sum of the number of individuals that received medicines included in the price scheme.
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company, Implementing partner: Axios International	Axios international keeps a record of the number of individuals that are benefiting from the patient assistance program. This data will then be reported to the Market Access team of Takeda.	Every month
31 Data processing	Company, Implementing partner: Axios International	Once a month, Axios International sums up the number of patients benefiting from the patients assistance program and reports the data to the Market Access team of Takeda. Staffs in charge of the program in the Market Access team of Takeda review and validate the data submitted by Axios International as necessary.	Ongoing
32 Data validation		Staffs in charge of the program in the Market Access team of Takeda will review and validate the data submitted by Axios International on a regular basis.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018
2 Number of patients reached with pricing scheme	---	---

Comments: N/A

ITEM	DESCRIPTION
Definition	Percentage patients on appropriate treatment (according to standard treatment guidelines related to NCDs) among the total number of patients with NCDs visiting the facility.
Method of measurement	<p>CALCULATION</p> <p>Number of patients treated according to standard treatment guidelines related to NCDs visiting the facility</p> <p>Total number of patients with NCDs visiting the facility</p>
28 Data source	Non-routine Program Data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company, Implementing partner: Axios International	A third party not involved in the initial treatment of patients benefiting from our program, reviews the case files of patients prescribed Adcetris to see if it is in accordance with the treatment guidelines. The third party keeps a record of those receiving appropriate treatment.	Every month
31 Data processing	Company, Implementing partner: Axios International	Axios International calculates the proportion of patients on appropriate treatment based on the review of the appropriateness of patients' treatment by a third party and reports the data to the Market Access team of Takeda. Staffs in charge of the program in the Market Access team of Takeda review and validate the data submitted by Axios International on a regular basis.	Ongoing
32 Data validation		Staffs in charge of the program in the Market Access team of Takeda review and validate the data submitted by Axios International on a regular basis.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018
3 Patients on appropriate treatment	---	---

Comments: N/A

Appendix

This program report is based on the information gathered from the Access Observatory questionnaire below.

Program Description

PROGRAM OVERVIEW

1 Program Name

2 Diseases program aims to address:

Please identify the disease(s) that your program aims to address (select all that apply).

3 Beneficiary population

Please identify the beneficiary population of this program (select all that apply).

4 Countries

Please select all countries that this program is being implemented in (select all that apply).

5 Program Start Date

6 Anticipated Program Completion Date

7 Contact person

On the public profile for this program, if you would like to display a contact person for this program, please list the name and email address here (i.e. someone from the public could email with questions about this program profile and data).

8 Program summary

Please provide a brief summary of your program including program objectives (e.g., the intended purposes and expected results of the program; if a pilot program, please note this). Please provide a URL, if available. Please limit replies to 750 words.

PROGRAM STRATEGIES & ACTIVITIES

9 Strategies and activities

Based on the BUSPH Taxonomy of Strategies, which strategy or strategies apply to your program (please select all that apply)?

10 Strategy by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g. some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

11 Company roles

Please identify all pharmaceutical companies, including yours, who are collaborating on this program:

What role does each company play in the implementation of your program?

12 Funding and implementing partners

Please identify all funding and implementing partners who are supporting the implementation of this program (Implementing partners is defined as either an associate government or non-government entity or agency that supplements the works of a larger organization or agency by helping to carry out institutional arrangements in line with the larger organization's goals and objectives.)

a. What role does each partner play in the implementation of your program? Please give background on the organization and describe the nature of the relationship between the organization and your company. Describe the local team's responsibilities for the program, with reference to the program strategies and activities. (response required for each partner selected).

- b. For each partner, please categorize them as either a Public Sector, Private Sector, or Voluntary Sector partner. (Public Sector is defined as government; Private Sector is defined as A business unit established, owned, and operated by private individuals for profit, instead of by or for any government or its agencies. Generation and return of profit to its owners or shareholders is emphasized; Voluntary Sector is defined as Organizations whose purpose is to benefit and enrich society, often without profit as a motive and with little or no government intervention. Unlike the private sector where the generation and return of profit to its owners is emphasized, money raised or earned by an organization in the voluntary sector is usually invested back into the community or the organization itself (ex. Charities, foundations, advocacy groups etc.))

c. Please provide the URL to the partner organizations' webpages

13 Funding and implementing partners by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g., some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have selected from above (funding and implementing partners), please identify which country/countries these apply.

14 Stakeholders

Please describe how you have engaged with any of these local stakeholders in the planning and/or implementation of this program. (Stakeholders defined as individuals or entities who are involved in or affected by the execution or outcome of a project and may have influence and authority to dictate whether a project is a success or not (ex. Ministry of Health, NGO, Faith-based organization, etc.). Select all that apply.

- Government, please explain
- Non-Government Organization (NGO), please explain
- Faith-based organization, please explain
- Commercial sector, please explain
- Local hospitals/health facilities, please explain
- Local universities, please explain
- Other, please explain

LOCAL CONTEXT, EQUITY & SUSTAINABILITY

15 Local health needs addressed by program

Please describe how your program is responsive to local health needs and challenges (e.g., how you decided and worked together with local partners to determine that this program was appropriate for this context)?

a How were needs assessed

b Was a formal need assessment conducted

(Yes/No) If yes, please upload file or provide URL.

16 Social inequity addressed

Does your program aim to address social inequity in any way (if yes, please explain). (Inequity is defined as lack of fairness or justice. Sometime 'social disparities,' 'structural barriers' and 'oppression and discrimination' are used to describe the same phenomenon. In social sciences and public health social inequities refer to the systematic lack of fairness or justice related to gender, ethnicity, geographical location and religion. These unequal social relations and structures of power operate to produce experiences of inequitable health outcomes, treatment and access to care. Health and social programs are often designed with the aim to address the lack of fairness and adjust for these systematic failures of systems or policies.)*

*Reference: The definition was adapted from Ingram R et al. Social Inequities and Mental Health: A Scoping Review. Vancouver: Study for Gender Inequities and Mental Health, 2013.

17 Local policies, practices, and laws considered during program design

How have local policies, practices, and laws (e.g., infrastructure development regulations, education requirements, etc.) been taken into consideration when designing the program?

18 How diversion of resources from other public health priorities are avoided

Please explain how the program avoids diverting resources away from other public health priorities? (e.g. local human resources involved in program implementation diverted from other programs or activities).

19 Program provides health technologies

Does your program include health technologies (health technologies include medical devices, medicines, and vaccines developed to solve a health problem and improve quality of lives)? (Yes/No)

20 Health technology(ies) are part of local standard treatment guidelines

Are the health technology(ies) which are part of your program part of local standard treatment guidelines? (Yes/No) If not, what was the local need for these technologies?

21 Health technologies are covered by local health insurance schemes

Does your program include health technologies that are covered by local health insurance schemes? (Yes/No) If not, what are the local needs for these technologies?

22 Program provides medicines listed on the National Essential Medicines List

Does your program include medicines that are listed on the National Essential Medicines List? (Yes/No) If not, what was the local need for these technologies?

23 Sustainability plan

If applicable, please describe how you have planned for sustainability of the implementation of your program (ex. Creating a transition plan from your company to the local government during the development of the program).

ADDITIONAL PROGRAM INFORMATION

24 Additional program information

Is there any additional information that you would like to add about your program that has not been collected in other sections of the form?

a Potential conflict of interest discussed with government entity

Have you discussed with governmental entity potential conflicts of interest between the social aims of your program and your business activities? (Yes/No) If yes, please provide more details and the name of the government entity.

25 Access Accelerated Initiative participant

Is this program part of the Access Accelerated Initiative? (Yes/No)

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Is your company a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)? (Yes/No)

