For information
on 23.6.2022

HAB-P322

Hospital Authority

Annual Report on the Operation of the Community Care Fund Medical Assistance Programmes

Advice Sought

Members are invited to note the annual report on the operation of the Community Care Fund (CCF) Medical Assistance Programmes in 2021/22[1] of which the Hospital Authority (HA) is the implementing agency under the supervision of the Food and Health Bureau (FHB). The various recommendations for the respective drugs / indications / medical devices for coverage in the CCF Medical Assistance Programmes had the support of the relevant governance platforms, and had been reported to the Medical Services Development Committee (MSDC) as appropriate[2].

Background

2. The CCF is a trust fund established in early 2011 under the Secretary for Home Affairs Incorporation Ordinance (Cap. 1044) with the Secretary for Home Affairs Incorporated as its trustee. Its main objective is to provide assistance to people facing financial difficulties, in particular those who fall outside the social safety net or those within the safety net but still have special circumstances that are not covered. In addition, the CCF may consider introducing programmes on a pilot basis to help the Government identify those measures that can be considered for incorporation into its regular assistance and service programmes. Following the re-establishment of the Commission on Poverty (CoP) by the Government in December 2012, the CCF has been integrated into the work of the CoP since 2013. The CCF Task Force under the CoP co-ordinates and oversees the implementation of CCF medical assistance programmes, draws up new projects and reports to the CoP on its workplans and progress as and when appropriate. The CCF has launched different assistance programmes covering the medical, education, welfare, home affairs and housing areas since its establishment in 2011. HA is the implementing agency of the three

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[1] The last annual report on the operation of the CCF Medical Assistance Programmes (2020/21) was submitted to the Board on 24 June 2021 via Hospital Authority Board (HAB) Meeting Paper No. 311.

[2] Via MSDC Paper No. 629 on "Introduction of New Drugs / Indications to be Covered by Samaritan Fund and Community Care Fund Medical Assistance Programmes from Second Quarter of 2021" discussed on 23 April 2021; MSDC Paper No. 639 on "Introduction of New Drugs / Indications to be Covered by Samaritan Fund and Community Care Fund Medical Assistance Programmes from Fourth Quarter of 2021" discussed on 11 October 2021; and MSDC-Paper No. 662 on "Introduction of New Drugs / Indications and Non-Drug Items to be Covered by Samaritan Fund and Community Care Fund Medical Assistance Programmes from Second Quarter of 2022" discussed on 22 April 2022.

CCF Medical Assistance Programmes under the supervision of the FHB. The three CCF Medical Assistance Programmes are:

(a) CCF Medical Assistance Programme (First Phase Programme) ("First Phase Programme");

(b) Subsidy for Eligible Patients to Purchase Ultra-expensive Drugs (Including Those for Treating Uncommon Disorders) ("UED Programme"); and

(c) Subsidy for Eligible Patients of HA to Purchase Specified Implantable Medical Devices for Interventional Procedures ("MD Programme").

The Programmes aim to provide subsidy for needy and eligible patients to purchase specified self-financed cancer drugs, ultra-expensive drugs and specified implantable medical devices for interventional procedures. The background information, governance of CCF Medical Assistance Programmes and the list of items covered by the three Programmes with effect from end May 2022 are in **Annexes 1 to 4 respectively**.

Coverage and Application Statistics

Changes in Coverage in 2021/22 and 2022/23

3. Having regard to changes in scientific evidence, cost effectiveness, technology advancement in treatment options, and changes in service provisions, HA will continue to follow the latest medical development with a view to including suitable drugs or items to the coverage of the Programmes according to the established mechanism.

4. To shorten the total lead time for introducing new drugs / medical devices to the CCF Medical Assistance Programme, CoP endorsed in October 2019 to streamline the approval process for introducing new drugs / medical devices to the three CCF Medical Assistance Programmes starting from 2020/21. Under the streamlined procedure, the CoP will, subject to its approval of an annual indicative budget for each programme, delegate the authority to the CCF Task Force Chairperson to grant final approval to the lists of recommended new drugs and medical devices.

5. As at 31 March 2021, the First Phase Programme and the UED Programme covered 33 self-financed cancer drugs and four ultra-expensive drugs respectively, while the MD Programme covered six medical devices. As supported by the HA CCF Administration Committee, and approved by relevant authorities of CCF, the changes in the coverage of the three Programmes in 2021/22 and 2022/23 (up to end May 2022) are summarised as follows:

Programme		Change in 2021/22 [3]	Changes in 2022/23 [4] *(Up to end May 2022)*
First Phase Programme	**New drugs**	- three drugs *(Olaparib for ovarian cancer; Gemtuzumab Ozogamicin for acute myeloid leukaemia; and Ipilimumab (in combination with Nivolumab) for renal cell carcinoma)*	Nil
	New or relaxed indications	- four indications *(for Pembrolizumab, Osimertinib, Dabrafenib and Trametinib, and Nivolumab)*	- one indication *(for Pembrolizumab)*
	Repositioning of drugs to Samaritan Fund (SF)	- two drugs/indications *(Pertuzumab for metastatic breast cancer and Sunitinib for gastrointestinal stromal tumour[5])*	- four drugs/indications *(Osimertinib[6] and Alectinib for lung cancer, Bendamustine for chronic lymphocytic leukaemia and Pazopanib for renal cell carcinoma)*
UED Programme	**New drugs**	- two drugs *(Tisagenlecleucel and Tafamidis[7])*	Nil
	New or relaxed indications	Nil	- one indication *(Nusinersen for spinal muscular atrophy)*
	Repositioning of drugs/ indications to SF	Nil	Nil
MD Programme	**New items**	Nil	- one medical device *(Transcatheter Tricuspid Valve Repair System)*
	Expansion / modification of indications	- one indication *(for Percutaneous Pulmonary Valve Implantation)*	- one indication *(Transcatheter Valve Implantation[8])*

[3] Reported to MSDC via MSDC Paper No. 629 and MSDC Paper No. 639.

[4] Reported to MSDC via MSDC Paper No. 662.

[5] Sunitinib is still under the coverage of First Phase Programme for another indication of renal cell carcinoma.

[6] Osimertinib is still under the coverage of First Phase Programme for first line treatment of adult patients with epidermal growth factor receptor mutation positive non-small cell lung cancer with central nervous system metastases.

[7] Upon implementation of the new drug/indication, the name of the oral formulation for treatment of polyneuropathy has been renamed as "Tafamidis meglumine". According to the HA Drug Formulary, Tafamidis meglumine and Tafamidis are listed as two drug entities.

[8] With the expansion of indication, name of this item has been updated as "Transcatheter Valve Implantation". Such item replaced two previously supported items, namely "Transcatheter Aortic Valve Implantation (TAVI)" and "Valve-in-valve Transcatheter Aortic Valve Implantation (VIV - TAVI)".

6. Details of the above new drugs/indications are set out in **Annex 5**; while the chronology of re-positioning of items from CCF Medical Assistance Programme to SF and Special Drugs of HA Drug Formulary is in **Annex 6**. Apart from inclusion of new drugs and indications, clinical guidelines of a number of covered drugs were relaxed or revised with details in **Annex 7**.

7. The First Phase Programme and the UED Programme covered 35 self-financed cancer drugs and six ultra-expensive drugs as at 31 March 2022 respectively, while the MD Programme covered six implantable medical devices. With the changes to the coverage in 2022/23 in end May 2022, **32 self-financed drugs, six ultra-expensive drugs** and **six implantable medical devices** are currently covered by the First Phase Programme, the UED Programme and the MD Programme respectively.

Approved Applications and Amount of Subsidy Granted

8. For the financial year 2021/22 (from 1 April 2021 to 31 March 2022), the number of approved applications, the total amount of subsidy granted and average amount of subsidy granted per application for the three CCF Medical Assistance Programmes are summarised as follows:

Programme	**Number of approved applications**	**Total amount of subsidy granted ($ million)**	**Average amount of subsidy granted per application ($)**
First Phase Programme	3 216	743.06	231,050
UED Programme	43	81.37	1,892,410
MD Programme	129	33.31	258,210

Big Spenders of Drugs under First Phase Programme

9. The big spenders under the First Phase Programme in 2021/22 were Pembrolizumab for lung cancer, Osimertinib for lung cancer and Bevacizumab for colorectal cancer. The total amount of subsidy granted for these drugs/indications was $347.65 million in 2021/22, which accounted for 47% of the total amount of subsidy granted for drug applications. The average amount of subsidy granted per application for these drugs/indications was around $287,000 in 2021/22.

Financial Position

2021/22 Draft Audited Accounts for the three Medical Assistance Programmes

10. The draft audited accounts of the three CCF Medical Assistance Programmes for the year ended 31 March 2022 are submitted to Members for approval via the

Administrative and Operational Meeting Paper No. 1763 on "2021/22 Audited Accounts of the Community Care Fund Medical Assistance Programmes".

2022/23 Annual Indicative Budgets for the three Medical Assistance Programmes

11. In accordance with the streamlined approval process for three Programmes as mentioned in paragraph 4, the 2022/23 indicative budgets for approved subsidy and administrative cost budgets of the three Programmes were supported and approved by the CCF Task Force and CoP on 1 November and 10 November 2021 respectively. Details are summarised as follows:

Programmes / **Budget**	**First Phase Programme ($ million)**	**UED Programme ($ million)**	**MD Programme ($ million)**	**Total ($ million)**
Indicative budget for approved subsidy [9]	1,331.00	276.00	78.00	1,685.00
Administrative cost Budget [10] *(Detailed breakdown of the administrative cost budget of the Programmes can be found at **Annex 8**)*	66.55	13.80	3.90	84.25

Quality Assurance

Clinical Audit

12. Clinical audit has been introduced to ensure that the referrals from doctors for CCF assistance are in compliance with the prevailing clinical guidelines. Taken into account the number of approved cases and amount of subsidy granted in the past year, Pembrolizumab for lung cancer and Impella for high-risk Percutaneous Coronary Intervention (PCI) Procedures had been selected for clinical audit. For applications approved in 2020/21, a total of 14 cases[11] of Pembrolizumab and seven cases[11] of Impella were selected for audit. The clinical audits are in progress and the findings will be reported to the HA CCF Administration Committee.

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[9] With a buffer of 15% to budget requirement for approved subsidy, as contingency.

[10] Covering staff cost, audit fee and other administrative fee, and is capped at 5% of the indicative budget for approved subsidy plus additional budget for the year, if any.

[11] The set target of selecting 5% of the approved cases of the drug had been achieved.

Financial Assessment Audit

13. Financial assessment audits are conducted to ensure that the financial assessment of CCF applications by Medical Social Services Units (MSSUs) follows the established guidelines, and to make recommendations for improvement where appropriate.

14. For applications made from 1 January 2021 to 31 December 2021, a total of 82 CCF applications[12] were selected for audit through peer review of the financial assessment documents by the Executive Assistants of the MSSUs in different hospitals, with support of respective officers of HA Head Office (HO). Of the aforesaid, 79 applications, representing 96% of all selected cases audited were in full compliance to the essential areas listed in the existing guidelines such as proof of identity of patient, presence of patient's signature in declaration. Among all the audited applications, only one case was found to have subsidy amount affected and debt recovery by prevailing procedures was completed. The hospital management concerned will be informed of the audit result accordingly.

15. The findings will be reported to different governance platforms, including the HA CCF Administration Committee and Medical Social Services Units Liaison meeting, as appropriate. The report will also be circulated to all MSSUs and the Headquarter of Social Welfare Department. Improvement measures had been taken by respective MSSUs, which included staff engagement; enhancement of internal checking and monitoring system.

Post-Approval Check

16. Post-approval checking (PAC) mechanism is in place for detecting and deterring potential fraud and abuse so as to achieve the ultimate objective of ensuring the use of public money is safeguarded. For applications approved in 2020/21 and 2021/22, a total of 3 317 cases[13] were selected for checking by Cluster Checking Units. Details of the outcome of PAC of the CCF Medical Assistance Programmes will be reported to the Board in the fourth quarter of 2022 together with the outcome of PAC of SF and Medical Fee Waiving.

Publicity of CCF

17. To enhance publicity of the First Phase Programme, UED Programme and MD Programme, HA posts application statistics, such as the cumulative number of approved applications and subsidy amount, on the HA's webpage on a monthly basis. HA has also arranged both internal and external publicity measures. Guidelines and relevant documents are promulgated to frontline staff as and when necessary. External publicity measures include publication of articles in patient newsletters, updating of CCF webpage on HA's

[12] The set target of selecting 5% of the approved non-CSSA cases, which involved (a) all approved subsidy amount for non-drug application and (b) approved subsidy ≥ $300,000 for drug application, was achieved.

[13] The set targets of selecting 100%, 10%-25% and 5-10% of approved non-CSSA cases for high, medium and low risk applications respectively had been achieved. The corresponding subsidy amount of applications of high, medium and low risk levels are: $300,000 or more, $100,000 to below $300,000, and below $100,000.

website, enhancing publicity through the "Smart Patient Website" of HA and patient forums, and distributing leaflets at HA hospitals and clinics.

18. Medical Fee Assistance Application (App), a one-stop portal integrated with the Payment section of HA Go, has been launched since late April 2022 for optimising patients' experience in applying for medical fee assistance (including SF and CCF Medical Assistance Programmes) and facilitating communication with patients to minimise unwitting under-reporting. With this App, patients are able to make a preliminary assessment of financial eligibility for applying medical fee assistance programmes with relevant multi-media information, such as videos introducing medical fee assistance programmes and PAC; keep track of application progress and receive notifications via 'Push Messages' for updates about their applications; and review the details of the approved subsidy and utilisation to facilitate their preparation for renewing their applications for financial assistance of drug items. To ensure timely communication with patients, reminders will be sent to patients via the App upon issuance of written notification letter for PAC.

Hospital Authority
HAB\PAPER\322
16 June 2022

Annex 1 to HAB-P322

Background information on
Community Care Fund (CCF) Medical Assistance Programmes

Objective

The CCF is a trust fund established in early 2011 under the Secretary for Home Affairs Incorporation Ordinance (Cap. 1044) with the Secretary for Home Affairs Incorporated as its trustee. Its main objective is to provide assistance to people facing financial difficulties, in particular those who fall outside the social safety net or those within the safety net but still have special circumstances that are not covered. In addition, the CCF may consider introducing programmes on a pilot basis to help the Government identify those measures that can be considered for incorporation into its regular assistance and service programmes. The CCF has since 2013 been integrated into the work of the reinstated Commission on Poverty (CoP)[1]. The CCF Task Force, set up under the CoP as chaired by the Chief Secretary for Administration, is responsible for advising the CoP on the CCF's various arrangements (including investment, finance and administrative operations), as well as the formulation of assistance programmes, the co-ordination and overseeing of the implementation of assistance programmes, and the evaluation of their effectiveness.

2. Since its establishment, CCF has rolled out different assistance programmes covering the medical, education, welfare, home affairs and housing areas for various target beneficiary groups including children, elderly persons, persons with disabilities, patients, new arrivals and ethnic minorities, etc.

3. Currently, HA is responsible for administering three CCF Medical Assistance Programmes under the supervision of the Food and Health Bureau (FHB). The three programmes are summarised as below:

(a) **First Phase Programme**[2] was introduced on 1 August 2011. It provides financial assistance to HA patients for purchasing specified self-financed (SFI) cancer drugs that have not been covered by the Samaritan Fund (SF) safety net but have been rapidly accumulating medical scientific evidence and with relatively higher efficacy. The prevailing mechanism for SF applications, including referral procedures, financial assessment criteria, and

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[1] In late 2010, the Chief Executive appointed the Steering Committee on the CCF to oversee and co-ordinate the work of the CCF. An Executive Committee and four Subcommittees (Education, Home Affairs, Medical and Welfare) were set up under the Steering Committee to support the operation of the CCF. The terms of the above-mentioned committees/ subcommittees ended in end 2012 and the CCF has since 2013 been integrated into the work of the reinstated CoP. The fourth term CoP has commenced on 1 July 2020. Two Task Forces have been set up under the fourth term CoP, namely the Community Care Fund Task Force and Social Innovation and Entrepreneurship Development Fund Task Force.

[2] The Second Phase Programme, rolled out on 16 January 2012, aimed to provide subsidy to needy patients who marginally fall outside the SF safety net for the use of specified SFI drugs. It complemented the SF by providing additional subsidy to HA patients by reducing their maximum contribution ratio from 30% to 20% of their household annual disposable financial resources (ADFR) to use the specified SFI drugs supported by the SF. The Second Phase Programme had been approved by the Government for incorporation into the Government's regular assistance programme, i.e. the SF, with effect from 1 September 2012. Upon regularisation, the Second Phase Programme ceased operation on 31 August 2012.

processing/approving of applications, has been adopted for the First Phase Programme.

(b) **Subsidy for Eligible Patients to Purchase Ultra-expensive Drugs (Including Those for Treating Uncommon Disorders) (UED Programme)** was introduced on 1 August 2017. It provides financial assistance to needy HA patients who meet specific clinical requirement to use those ultra-expensive drugs, including those for treatment of uncommon disorders, which have not yet been brought into SF safety net.

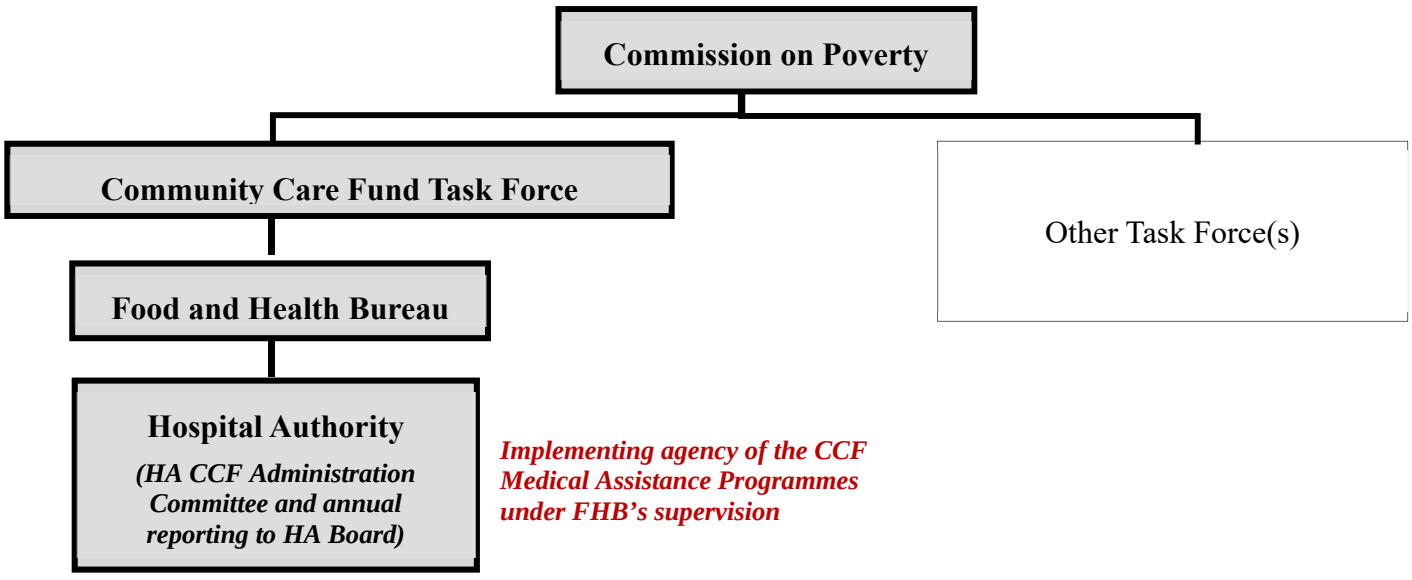
(c) **Subsidy for Eligible Patients of HA to Purchase Specified Implantable Medical Devices for Interventional Procedures (MD Programme)** was introduced on 1 August 2017. It provides financial assistance to needy HA patients to have early access to specified implantable medical devices for interventional procedures which have not yet been incorporated as part of HA's standard services due to the need for accumulating further evidence for cost-effectiveness.

Eligibility

4. To be eligible for financial assistance from the CCF Medical Assistance Programmes, HA patients must fulfill the clinical indications of the required drug/item as well as the identity requirement, and pass the means test.

Governance

5. Under the CCF Medical Assistance Programmes, HA, being the implementing agency of the three Medical Assistance Programmes under the supervision of FHB, is required to report progress of the Medical Assistance Programmes to the CCF Task Force and CoP. The governance structure in HA for the administration of CCF Medical Assistance Programmes as well as the delegation and approving authority were approved by the Board at its meeting on 31 May 2011 via Administrative and Operational Meeting Paper No. 769. The governance of CCF medical assistance programmes is as follows:



Mechanism of introducing new items / technology

6. The mechanism of introducing new drugs /medical devices is set out as follows:

Mechanism for consideration of the coverage of drugs / medical devices in the CCF[3]

An annual indicative budget for each Programme is submitted to CoP for approval before the beginning of each financial year*

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Lists of self-financed drugs / medical devices with potential to be covered in the funding scope of CCF Medical Assistance Programmes

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Recommendation on prioritisation made by **Drug Management Committee** for drugs**,** and **Medical Device Advisory Committee** for medical devices

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Evaluation by **The HA CCF Administration Committee** on the priority of new items for coverage by the Fund

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Supported list of new drugs and medical devices is submitted to **CCFTF Chairperson for final approval** and the approved list of drugs and medical devices will be circulated to CCFTF and CoP for information

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After approval by the Chairperson of the CCFTF, the new drugs and medical devices will be implemented once the other necessary preparation (e.g. formulation of clinical guidelines) is completed

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Report to **HA Board**

Remarks:

* The CoP will also grant approval-in-principle for new drugs/medical devices recommended in future on the condition that -

(a) the financial requirement for these new drugs/medical devices will be within the approved annual indicative budget and the scope of coverage of respective Programme; and

(b) these new drugs/medical devices will have gone through the established review mechanism in HA.

[3] The mechanism was discussed and endorsed at CoP Meeting on 29 October 2019 and took effective in 2020/21.

Annex 2 to HAB-P322

Drugs Covered by the First Phase Programme
(As at end May 2022)

Self-financed drugs:
(Items shown in **bold** *are newly introduced in 2021/22 while those shown in italics are newly introduced in 2022/23)*

No.	Drug	Designated type of cancer	Designated clinical indications
1	Abemaciclib	Breast cancer	For treatment of hormone receptor (HR)+ve, human epidermal growth factor receptor 2 (HER2)-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy
2a	Abiraterone	Prostate cancer	For metastatic castration resistant prostate cancer (mCRPC) progressed on or after docetaxel-based chemotherapy regimen
2b			For the treatment of adult men with mCRPC who are unsuitable for Docetaxel treatment on the basis of predicted intolerance to Docetaxel
3	Atezolizumab	Lung cancer	For Epidermal growth factor receptor (EGFR)-ve and ALK-ve NSCLC progressed on or following platinum-based chemotherapy
4	Axitinib	Renal cell carcinoma	For patients with advanced renal cell carcinoma (RCC), whose disease has progressed on or after first-line treatment
5a	Bevacizumab	Colorectal cancer	First line treatment of RAS mutant metastatic colorectal cancer in combination with chemotherapy in adult patients indicated for intensive treatment OR First-line treatment of RAS wild type metastatic colorectal cancer in combination with chemotherapy in adult patients indicated for intensive treatment who are unsuitable for or intolerant to Cetuximab / Panitumumab
5b		Epithelial ovarian/fallopian tube/ primary peritoneal cancer	With carboplatin and paclitaxel for front-line advanced epithelial ovarian / fallopian tube / primary peritoneal cancer
6a	Brentuximab Vedotin	Lymphoma	For the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (RR/HL): (i) following autologous stem cell transplant (ASCT), or (ii) following at least two prior therapies when ASCT or multi - agent chemotherapy is not a treatment option
6b			For the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma
6c			For the treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy

No.	Drug	Designated type of cancer	Designated clinical indications
7	Brigatinib	Lung cancer	For the treatment of patients with ALK+ve, NSCLC who have progressed on Crizotinib and intolerant to Ceritinib, or who have CNS-progression after Crizotinib
8	Ceritinib	Lung cancer	For adult patients with ALK+ve advanced NSCLC previously treated with Crizotinib
9	Dabrafenib and Trametinib	Skin cancer	For the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma
10			**For the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection**
11	Durvalumab	Lung cancer	For unresectable, stage III NSCLC with at least 1% of tumour cells expressing PD-L1, whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy
12a	Enzalutamide	Prostate cancer	For mCRPC progressed on or after docetaxel-based chemotherapy regimen
12b			For the treatment of adult men with mCRPC who are unsuitable for Docetaxel treatment on the basis of predicted intolerance to Docetaxel
13	Everolimus	Breast cancer	For HR+ve HER2-ve advanced breast cancer, in combination with Exemestane, in postmenopausal women with bone-only disease after recurrence or progression following a non-steroidal aromatase inhibitor
14	**Gemtuzumab Ozogamicin**	**Leukaemia**	**In combination with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL)**
15	Inotuzumab Ozogamicin	Leukaemia	As monotherapy for the treatment of transplant-eligible adult patients with relapsed or refractory CD22-positive B cell acute lymphoblastic leukaemia (ALL) that is either Philadelphia chromosome negative, or Philadelphia chromosome positive failing at least 1 prior tyrosine kinase inhibitor (TKI) treatment
16	Ixazomib	Multiple myeloma	In combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy
17	Lenalidomide		
18	Lapatinib	Breast cancer	HER2+ve advanced breast cancer with prior therapy including an anthracycline, a taxane, and Trastuzumab

No.	Drug	Designated type of cancer	Designated clinical indications
19	Lenvatinib	Liver cancer	For first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
20a	**Nivolumab**	Skin cancer	As monotherapy for BRAF V600 wild-type unresectable or metastatic melanoma
20b			For adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection
20c		Lung cancer	For EGFR-ve and ALK-ve NSCLC progressed on or following platinum-based chemotherapy
20d		**Head and Neck Cancer**	**For the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum based therapy**
20e	**Nivolumab and Ipilimumab**	**Renal cell carcinoma**	**For the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma**
21			
22	Obinutuzumab	Leukaemia	In combination with Chlorambucil for treatment of previously untreated CLL in adult patients with comorbidities making them unsuitable for full-dose Fludarabine or Bendamustine based therapy
23	**Olaparib**	**Epithelial ovarian/ fallopian tube /primary peritoneal cancer**	**As maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response after first-line platinum-based chemotherapy**
24	Osimertinib	Lung cancer	First line treatment of adult patients with EGFR mutation +ve NSCLC with CNS metastases
25	Palbociclib	Breast cancer	For treatment of HR+ve HER2-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy
26	Pegylated Liposomal Doxorubicin	Ovarian cancer	Second-line of platinum refractory or subsequent treatment of platinum resistant advanced ovarian cancer

No.	Drug	Designated type of cancer	Designated clinical indications
27a	***Pembrolizumab***	Lung cancer	For first-line treatment for metastatic NSCLC with high PD-L1 expression (Tumor Proportion Score >=50%) with no EGFR or ALK genomic tumor aberrations
27b		**Bladder cancer**	**Treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy**
27c		*Lymphoma*	*As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and Brentuximab Vedotin (BV), or who are transplant-ineligible and have failed BV* [4]
28	Ribociclib	Breast cancer	For treatment of HR+ve HER2-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy
29	Sunitinib	Renal cell carcinoma	First line treatment for advanced RCC
30	Trastuzumab	Gastric carcinoma	Combined with Cisplatin & Capecitabine or 5FU for HER2 overexpressed metastatic gastric disease (IHC2+ and confirmatory FISH+ result, or IHC3+) in treatment-naive patients for their metastatic disease
31	Trastuzumab emtansine (T-DM1)	Breast cancer	As monotherapy for HER2+ve metastatic breast cancer with prior Trastuzumab and/or taxane therapy for their metastatic disease
32	Vemurafenib	Skin cancer	As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma

[4] New indication introduced into the First Phase Programme with effect from end May 2022.

Annex 3 to HAB-P322

Drugs Covered by the Ultra-expensive Drugs Programme
(As at end May 2022)

Ultra-expensive Drugs
(Items shown in **bold** *are newly introduced in 2021/22 while those shown in italics are newly introduced in 2022/23)*

No.	Drug	Designated clinical indications
1	Dinutuximab Beta	Treatment of high-risk or relapse/refractory neuroblastoma
2	Eculizumab	Atypical haemolytic uraemic syndrome
3	*Nusinersen*	Infantile Onset Spinal Muscular Atrophy (SMA) / Childhood Onset SMA / *Pre-symptomatic SMA* [1]
4	Tafamidis Meglumine	For the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment
5	**Tafamidis** [2]	**For treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy**
6	**Tisagenlecleucel**	**Paediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukaemia that is refractory, in relapse posttransplant or in second or later relapse / Adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy**

[1] Relaxation of indication for existing drug with effect from end May 2022.

[2] Tafamidis (Vyndamax) is licensed for the indication of ATTR-CM. Tafamidis (Vyndamax) and Tafamidis (Vyndaqel) are two oral formulations of the first-in-class transthyretin stabilizer tafamidis. The CCF Programme supports Tafamidis (Vyndaqel) for the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment. Due to introduction of this new drug/indication, the drug entity for the drug (i.e. Tafamidis (Vyndaqel)) for treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy was revised from “Tafamidis” to “Tafamidis Meglumine”.

Annex 4 to HAB-P322

Medical Devices Covered by the Medical Devices Programme
(As at end May 2022)

Implantable Medical Devices
(Items shown in italics are newly introduced in 2022/23)

No.	Medical Devices
1	*Transcatheter Valve Implantation* [1]
2	MitraClip System
3	Percutaneous Pulmonary Valve implantation (PPVI)
4	Subcutaneous Implantable Cardioverter Defibrillator (S-ICD)
5	Impella for high-risk Percutaneous Coronary Intervention (PCI) Procedures
6	*Transcatheter Tricuspid Valve Repair System* [2]

[1] Expansion of clinical indication for medical device with effect from end May 2022. With the expansion of indication, name of this item has been updated as "Transcatheter Valve Implantation". Such item replaced two current items, namely "Transcatheter Aortic Valve Implantation (TAVI)" and "Valve-in-valve Transcatheter Aortic Valve Implantation (VIV - TAVI)".

[2] New medical device with effect from end May 2022.

Annex 5 to HAB-P322

Details of new drugs/indications/non-drug items introduced in 2021/22 and 2022/23 (Up to May 2022)

2021/22

(i) New drugs/indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Olaparib	New drug/indication	As maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response after first-line platinum-based chemotherapy	22 May 2021
2.	Gemtuzumab Ozogamicin	New drug/indication	In combination with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL)	4 Dec 2021
3.	Nivolumab and Ipilimumab	New drug/indication	For the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma	4 Dec 2021

- UED Programme

No.	Drugs	Change	Indications	Effective Date
1.	Tisagenlecleucel	New drug	Paediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukaemia that is refractory, in relapse post-transplant or in second or later relapse / Adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy	10 Apr 2021
2.	Tafamidis	New drug	For treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)	4 Dec 2021

(ii) New or relaxed indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Osimertinib	Relaxation of indication	First line treatment of adult patients with EGFR mutation +ve NSCLC with CNS metastases	22 May 2021
2.	Pembrolizumab	New indication to existing drug	Treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy	22 May 2021
3.	Dabrafenib and Trametinib	New indication to existing drug	For the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection	4 Dec 2021
4.	Nivolumab	New indication to existing drug	For the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum based therapy	4 Dec 2021

(iii) Expansion and Modification of indications for non-drug items under the coverage of the MD Programme

No.	Non-Drug items	Change	Indications	Effective Date
1.	Percutaneous Pulmonary Valve implantation (PPVI)	Expansion and modification of indication	Expansion and modification of the clinical indication for better alignment with international guidelines: - Symptomatic patients with severe pulmonary regurgitation alone (as defined by cardiac magnetic resonance imaging (MRI data) already warrants PPVI, and no additional supportive parameters is required - Definition of predominant stenotic lesion is modified in accordance with the international recommendations	22 May 2021

2022/23 (Up to May 2022)

(i) New or relaxed indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Pembrolizumab	New indication to existing drug	As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and Brentuximab Vedotin (BV), or who are transplant-ineligible and have failed BV	28 May 2022

- UED Programme

No.	Drugs	Change	Indications	Effective Date
1.	Nusinersen	Relaxation of indication for existing drug	Infantile Onset Spinal Muscular Atrophy (SMA) / Childhood Onset SMA/ Pre-symptomatic SMA	28 May 2022

(ii) New non-drug items / Expansion of indication for non-drug items under the coverage of the MD Programme

No.	Non-Drug items	Change	Indications	Effective Date
1.	Transcatheter Tricuspid Valve Repair System	New medical device	Severe Tricuspid Regurgitation	28 May 2022
2.	Transcatheter Valve Implantation	Expansion of indication	For severe aortic stenosis and all severe stenosis or regurgitation lesions where anchoring of these valves are possible, and the patient is at high risk for open heart surgery	28 May 2022

Annex 6 to HAB-P322

Chronology of Re-positioning of Items from Community Care Fund Medical Assistance Programme to Samaritan Fund & Special Drugs of HA Drug Formulary *(As at May 2022)*

- *To Samaritan Fund*

No.	Drug and Type of Cancer	Effective Date
1.	Rituximab for Chronic Lymphocytic Leukaemia (CLL)	Apr 2013
2.	Dasatinib for Acute Lymphoblastic Leukaemia (ALL)	Apr 2013
3.	Cetuximab for Colorectal Cancer (CRC)	Aug 2016
4.	Afatinib for Non-small cell lung cancer (NSCLC) - first-line treatment	Feb 2019
5.	Erlotinib for NSCLC – first-line treatment	Feb 2019
6.	Gefitinib for NSCLC – first-line treatment	Feb 2019
7.	Sorafenib for Liver Cancer	Dec 2020
8.	Pertuzumab for Breast Cancer	Dec 2021
9.	Sunitinib for Gastrointestinal Stromal Tumour (GIST)	Dec 2021
10.	Alectinib for NSCLC	May 2022
11.	Bendamustine for CLL	May 2022
12.	Osimertinib [#] for NSCLC - second-line treatment	May 2022
13.	Pazopanib for Renal Cell Carcinoma	May 2022

[#] Osimertinib is still under CCF for another indication – first-line treatment

- *To Special Drugs of HA Drug Formulary*

No.	Drugs and Designated Type of Cancer	Effective Date
1.	Pemetrexed for Lung Cancer	Apr 2019

Chronology of Re-positioning of Items from the Programme "Subsidy for Eligible Patients to Purchase Ultra-expensive Drugs (Including Those for Treating Uncommon Disorders)" to Samaritan Fund

No.	Drug and Type of Disease	Effective Date
1.	Eculizumab for Paroxysmal Nocturnal Haemoglobinuria (PNH)	Jul 2020

Annex 7 to HAB-P322

Details of relaxation/revision of clinical guidelines in 2021/22 and 2022/23 (Up to May 2022)

(i) 2021/22

- First Phase Programme

No.	Drugs	Indications	Revision	Effective Date
1	Atezolizumab	For EGFR-ve and ALK-ve metastatic non-small cell lung cancer (NSCLC) progressed on or following platinum-based chemotherapy	Modification on the clinical guidelines of Atezolizumab under CCF First Phase Programme due to introduction of new preparation 840mg	10 April 2021
2	Trastuzumab	Combined with Cisplatin & Capecitabine or 5FU for HER2 overexpressed metastatic gastric disease (IHC2+ and confirmatory FISH+ result, or IHC3+) in treatment-naive patients for their metastatic disease	Inclusion of biosimilars of Trastuzumab (Herzuma® and Kanjinti®)	10 April 2021
3	Palbociclib / Ribociclib / Abemaciclib	For treatment of HR+ve HER2-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy	Refinement on the section of "Previous Treatment"	10 April 2021
4	Dabrafenib and Trametinib	For the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma	Revision on clinical guidelines and referral form with addition of the following exclusion criterion in view of the new indication of adjuvant treatment to be introduced: *"Patients with prior adjuvant Dabrafenib or Trametinib therapy"*	4 Dec 2021
5	Osimertinib	First line treatment of adult patients with EGFR mutation +ve NSCLC with CNS metastases	Refinement on "Prescribing and Dispensing of the Drug"	4 Dec 2021

(ii) 2022/23 (Up to May 2022)

- First Phase Programme

No.	Drugs	Indications	Revision	Effective Date
1	Lenvatinib	For first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)	Update of maximum treatment period supported by CCF from "5 cycles" to "8 cycles", due to the revision of cap ceiling for Patient Access Programme from "140 days" to "224 days", with effect from 23 May 2022. The modification would only be applied to new patients enrolled to the programme on/after the effective date.	23 May 2022

Annex 8 to HAB-P322

Administrative cost budget for 2022/23 of the three Community Care Fund (CCF) Medical Assistance Programmes

Programmes / Budget	First Phase Programme ($ million)	UED Programme ($ million)	MD Programme ($ million)	Total ($ million)
Staff cost	56.56	11.73	3.31	71.60
Computer system	2.00	-	-	2.00
Audit fee	0.19	0.10	0.10	0.39
Others	1.15	0.59	0.10	1.84
Contingency	6.65	1.38	0.39	8.42
Total	**66.55**	**13.80**	**3.90**	**84.25**