For information on 29.6.2023

HAB-P335

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 2022/23[1] for which the Hospital Authority (HA) is the implementing agency under the supervision of the Health Bureau (HHB). 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 were 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 (currently known as Secretary for Home and Youth Affairs Incorporation Ordinance) (Cap. 1044) with the Secretary for Home Affairs Incorporated (currently known as the Secretary for Home and Youth 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 have special circumstances that are not covered. In addition, the CCF may consider introducing programmes on a pilot basis to help the Government identify 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

[1] The last annual report on the operation of the CCF Medical Assistance Programmes (2021/22) was submitted to the Board on 23 June 2022 via Hospital Authority Board (HAB) Meeting Paper No. 322.

[2] Via 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; MSDC Paper No. 675 on "Introduction of New Drugs / Indications and Non-Drug Items to be Covered by Samaritan Fund and Community Care Fund Medical Assistance Programmes from Fourth Quarter of 2022" discussed on 10 October 2022; and MSDC Paper No. 691 on "Introduction of New Drugs / Indications to be Covered by Samaritan Fund and Community Care Fund Medical Assistance Programmes from Second Quarter of 2023" discussed on 26 April 2023.

the medical, education, welfare, home affairs and housing areas since its establishment in 2011. HA is the implementing agency of the three CCF Medical Assistance Programmes under the supervision of the HHB:

(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 2023 are in **Annexes 1 to 4** respectively.

Coverage and Application Statistics

Changes in Coverage in 2022/23 and 2023/24

3. Having regard to changes in scientific evidence, cost effectiveness, technology advancement in treatment options and 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 Chairperson of the CCF Task Force to grant final approval to the lists of recommended new drugs and medical devices.

5. As at 31 March 2022, the First Phase Programme and the UED Programme covered 35 self-financed cancer drugs and six 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 2022/23 and 2023/24 (up to end May 2023) are summarised as follows:

Programme		Change in 2022/23 [3]	Changes in 2023/24 [4] *(Up to end May 2023)*
First Phase Programme	**New drugs**	- six drugs *(Lorlatinib for lung cancer; Acalabrutinib, and Polatuzumab Vedotin in combination with Rituximab and Bendamustine for lymphoma; and Neratinib for breast cancer)*	- three drugs *(Daratumumab in combination with Bortezomib for multiple myeloma; and Niraparib for epithelial ovarian / fallopian tube / primary peritoneal cancer)*
	New or relaxed indications	- four indications *(for Pembrolizumab, Atezolizumab and Bevacizumab)*	- two indications *(for Pembrolizumab)*
	Repositioning of drugs to Samaritan Fund (SF)	- 10 drugs/indications *(Osimertinib[5], Alectinib and Ceritinib for lung cancer; Bendamustine and Obinutuzumab for chronic lymphocytic leukaemia; Pazopanib and Axitinib for renal cell carcinoma; Abiraterone[6] and Enzalutamide for prostate cancer)*	- nine drugs/indications *(Nivolumab[7] and Dabrafenib in combination with Trametinib[8] for skin cancer; Palbociclib, Ribociclib, Everolimus and Trastuzumab emtansine (T-DM1) for breast cancer; Brentuximab Vedotin for lymphoma)*
UED Programme	**New drugs**	- one drug *(Risdiplam for spinal muscular atrophy)*	- two drugs *(Burosumab for X-linked hypophosphataemia; Ravulizumab[9] for paroxysmal nocturnal haemoglobinuria and atypical haemolytic uraemic syndrome)*
	New or relaxed indications	- one indication *(Nusinersen for spinal muscular atrophy)*	Nil

[3] Reported to MSDC via MSDC Paper No. 662 and MSDC Paper No. 675.

[4] Reported to MSDC via MSDC Paper No. 691.

[5] 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.

[6] Abiraterone is still under the coverage of First Phase Programme for the treatment of adult men with metastatic castration resistant prostate cancer (mCRPC) who are unsuitable for Docetaxel treatment on the basis of predicted intolerance to Docetaxel.

[7] Nivolumab is still under the coverage of First Phase Programme for another indication for treatment of skin cancer - for adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

[8] Dabrafenib & Trametinib are still under the coverage of First Phase Programme for another indication for treatment of skin cancer - for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.

[9] The exact time for introduction of Ravulizumab to the Ultra-expensive Drugs Programme depends on the availability of this drug in Hong Kong.

Programme		Change in 2022/23 [3]	Changes in 2023/24 [4] *(Up to end May 2023)*
MD Programme	**New items**	- one medical device *(Transcatheter Tricuspid Valve Repair System)*	Nil
	Expansion / modification of indications	- one indication *(Transcatheter Valve Implantation[10])*	Nil

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 34 self-financed cancer drugs and seven ultra-expensive drugs respectively as at 31 March 2023, while the MD Programme covered six implantable medical devices. With implementation of all the new drugs/indications and repositioning of a number of cancer drugs from First Phase Programme to SF as reported to the MSDC in April 2023, **32 self-financed drugs, nine ultra-expensive drugs**[9] and **six implantable medical devices** will be 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 2022/23 (from 1 April 2022 to 31 March 2023), 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	3 035	710.24	234,016
UED Programme	64	131.99	2,062,349
MD Programme	143	36.89	257,991

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

Big Spenders of Drugs under First Phase Programme

9. The big spenders under the First Phase Programme in 2022/23 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 $313.26 million in 2022/23, which accounted for 44% of the total amount of subsidy granted for drug applications. The average amount of subsidy granted per application for these drugs/indications was around $270,000 in 2022/23.

Financial Position

2022/23 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 2023 are submitted to Members for approval via the Administrative and Operational Meeting (AOM) Paper No. 1866 on "2022/23 Audited Accounts of the Community Care Fund Medical Assistance Programmes".

2023/24 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 2023/24 indicative budgets for approved subsidy and administrative cost budgets of the three Programmes were supported and approved by the CCF Task Force and CoP in October 2022 and December 2022 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 [11]	1,330.00	385.00	73.00	1,788.00
Administrative cost budget [12] *(Detailed breakdown of the administrative cost budget of the Programmes can be found at **Annex 8**)*	33.25	9.62	1.82	44.69

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

[12] Covering staff cost and other administrative fee, and is within the cap of 5% of the indicative budget for approved subsidy plus additional budget for the year, if any.

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. As reported to the Board in June 2022[1], applications approved in 2020/21 for (a) Pembrolizumab for first-line treatment for metastatic non-small cell lung cancer (NSCLC) with high PD-L1 expression (Tumor Proportion Score >=50%) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and (b) Impella for high-risk Percutaneous Coronary Intervention (PCI) Procedures were selected for clinical audit in view of the number of applications and amount of subsidy granted for these items. The audits were conducted through peer review of 14 selected cases[13] of Pembrolizumab for non-small cell lung cancer and seven cases for Impella by clinical audit teams comprising a number of clinicians of related specialty, with an aim to review whether the prevailing clinical guidelines were fulfilled during the referral process of CCF applications.

13. On the findings of the clinical audit, it was concluded that 13 out of 14 (93%) selected cases of Pembrolizumab fulfilled the prevailing clinical guidelines[14]; while all seven selected cases of Impella fulfilled the prevailing clinical guidelines. The audit reports were circulated to the relevant Coordinating Committees and Central Committees. As a follow up, apart from informing senior management of the concerned hospital of the non-compliant case, the referring doctor and designated endorser were reminded to observe the clinical guidelines during the referral process. The overpaid subsidy on the concerned CCF case was recovered from the concerned hospital.

14. Taken into account the number of approved cases and amount of subsidy granted in the past year, Osimertinib for lung cancer and MitraClip System had been selected for clinical audit. For applications approved in 2021/22, 21 cases of Osimertinib and three cases of MitraClip System were selected for audit[13]. The clinical audits are in progress and the findings will be reported to the HA CCF Administration Committee.

Financial Assessment Audit

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

16. For applications made from 1 January 2022 to 31 December 2022, a total of 69 CCF applications[15] were selected for audit through peer review of the financial assessment documents by the Executive Assistants of the MSSUs in different hospitals, with

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[13] The set target of selecting 5% of the approved cases of the drug or non-drug item had been achieved.

[14] It was found that Pembrolizumab treatment of one case had not been terminated accordingly despite the patient had completed 24 months of treatment. (According to the CCF clinical guidelines, treatment should be terminated if the patients completed 24 months (i.e. 35 cycles) of Pembrolizumab treatment.)

[15] 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.

support of respective officers of HA Head Office (HO). Of the aforesaid, 66 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. The remaining three cases were found to have the subsidy amount affected and debt recovery by prevailing procedures was completed. The hospital management concerned will be informed of the audit result accordingly.

17. The findings will be reported to different governance platforms, including the HA CCF Administration Committee and MSSUs Liaison meeting, as appropriate. The report will also be circulated to all MSSUs and the Headquarter of the 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

18. 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 2021/22 and 2022/23, a total of 3 396 cases [16] were selected for checking by Cluster Checking Units as at 30 April 2023. Details of the outcome of PAC of the CCF Medical Assistance Programmes will be reported to the Board in the fourth quarter of 2023 together with the outcome of PAC of SF and Medical Fee Waiving.

Publicity of CCF

19. To enhance publicity of the First Phase Programme, UED Programme and MD Programme, application statistics, such as the cumulative number of approved applications and subsidy amount, are posted 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 website, enhancing publicity through the "Smart Patient Website" of HA and patient forums, as well as distributing leaflets at HA hospitals and clinics.

20. 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. 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. Patients can also 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. Recently,

[16] 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.

a new feature has been introduced in the app to allow patients to upload documents for the financial assessment upon requests made by MSSU. To ensure timely communication with patients during PAC, reminders will be sent to patients via the App upon issuance of written notification letter for PAC.

Changes to Delegation of Authority (DoA)

21. The DoA for SF setting out the approval authority for funding applications and financial operations of the Fund was developed and approved by the HA Board in November 2007[17]. Following a thorough review of the DoA for SF conducted in 2022, changes to the DoA for approving funding applications and financial operations of SF, which are also applicable to CCF Medical Assistance Programmes as appropriate, were approved by the HA Board at its AOM held on 17 November 2022[18] with immediate effect. These changes have taken into account updates on or changes in operating activities, with the level of approval authority to include the following principles / areas:

(a) Matters requiring oversight by the HA Board will be reserved for the Board;

(b) Matters relating to the policy or administration of SF will be subject to the approval of Management Committee of Samaritan Fund (SFMC) pursuant to its term of reference;

(c) Matters relating to the day-to-day financial operation of SF, DoA will be updated to make them in line with those of the HA Finance Functions; and

(d) Matters relating to the funding applications of SF, the existing level of authority will largely remain unchanged, save for certain revisions made to reflect the latest approval authority or mechanism as agreed by SFMC and the existing practices.

22. Going forward, review of the DoA for SF and CCF Medical Assistance Programmes would be conducted every three years and changes to DoA would be presented to SFMC and HA CCF Administration Committee for endorsement respectively before seeking approval from the HA Board.

Hospital Authority
HAB\PAPER\335
21 June 2023

[17] Via AOM Paper No. 513 on "Governance of the Samaritan Fund".
[18] Via AOM Paper No. 1808 on" Annual Report on the Operation of the Samaritan Fund".

Annex 1 to HAB-P335

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 (currently known as Secretary for Home and Youth Affairs Incorporation Ordinance) (Cap. 1044) with the Secretary for Home Affairs Incorporated (currently known as the Secretary for Home and Youth 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, the Hospital Authority (HA) is responsible for administering three CCF Medical Assistance Programmes under the supervision of the Health Bureau (HHB). 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 fifth term CoP has commenced on 1 January 2023. Two Task Forces have been set up under the fifth 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.

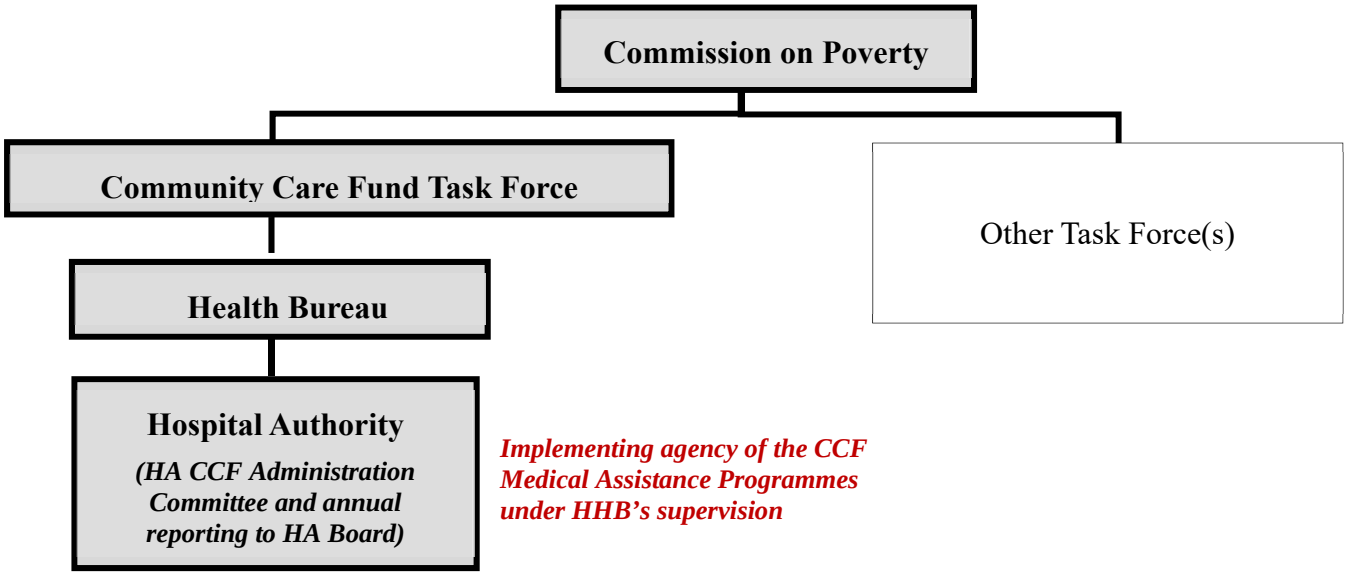
(c) **Subsidy for Eligible Patients of HA to Purchase Specified Implantable Medical Devices for Interventional Procedures (MD Programme)** was introduced on 1 August 2017. It provides financial assistance to needy HA patients to have early access to specified implantable medical devices for interventional 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 HHB, 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 HA 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-P335

Drugs Covered by the First Phase Programme
(As at end May 2023)

Self-financed drugs:
(Items shown in **bold** *are newly introduced in 2022/23 while those shown in italics are newly introduced in 2023/24)*

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
2	Abiraterone	Prostate cancer	For the treatment of adult men with metastatic castration resistant prostate cancer (mCRPC) who are unsuitable for Docetaxel treatment on the basis of predicted intolerance to Docetaxel
3	**Acalabrutinib**	**Lymphoma**	**For adult patients with relapsed or refractory mantle cell lymphoma**
4a	Atezolizumab	Lung cancer	For Epidermal growth factor receptor (EGFR)-ve and Anaplastic Lymphoma Kinase (ALK)-ve metastatic non-small cell lung cancer (NSCLC) progressed on or following platinum-based chemotherapy
4b			**As monotherapy for the first-line treatment of adult patients with metastatic NSCLC whose tumours have a PD-L1 expression >=50% tumour cells (TC) and who do not have EGFR mutant or ALK-positive NSCLC**
4c	**Atezolizumab and Bevacizumab**	**Hepatocellular carcinoma**	**For the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy**
5a			
5b	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
5c		Epithelial ovarian / fallopian tube / primary peritoneal cancer	With carboplatin and paclitaxel for front-line advanced epithelial ovarian / fallopian tube / primary peritoneal cancer
6	Brigatinib	Lung cancer	For the treatment of patients with ALK+ve, metastatic NSCLC who have progressed on Crizotinib and intolerant to Ceritinib, or who have central nervous system (CNS)-progression after Crizotinib

No.	Drug	Designated type of cancer	Designated clinical indications
7 8	Dabrafenib and Trametinib	Skin cancer	For the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection
9 10	*Daratumumab and Bortezomib*	*Multiple myeloma*	*In combination with thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma (MM) who are eligible for autologous stem cell transplant*
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
12	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)
13	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
14 15	Ixazomib and Lenalidomide	Multiple myeloma	In combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy
16	Lapatinib	Breast cancer	HER2+ve advanced breast cancer with prior therapy including an anthracycline, a taxane, and Trastuzumab
17	Lenvatinib	Liver cancer	For first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
18	**Lorlatinib**	**Lung cancer**	**For the treatment of patients with ALK-positive metastatic NSCLC whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or alectinib or ceritinib or brigatinib as the first ALK inhibitor therapy for metastatic disease**
19	**Neratinib**	**Breast cancer**	**For extended adjuvant treatment of adult patients with early-stage HR+ve, HER2+ve, breast cancer (>1cm or lymph node-positive) and who completed adjuvant trastuzumab-based therapy less than one year ago**
20	*Niraparib*	*Epithelial ovarian / fallopian tube / primary peritoneal cancer*	*As monotherapy for the maintenance treatment of adult patients with advanced Homologous Recombination Deficiency (HRd) BRCA wild-type epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response following completion of first-line platinum-based chemotherapy*

No.	Drug	Designated type of cancer	Designated clinical indications
21a	Nivolumab	Skin cancer	For adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection
21b		Lung cancer	For EGFR-ve and ALK-ve metastatic NSCLC progressed on or following platinum-based chemotherapy
21c		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
21d	Nivolumab and Ipilimumab	Renal cell carcinoma	For the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma
22			
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	Pegylated Liposomal Doxorubicin	Ovarian cancer	Second-line of platinum refractory or subsequent treatment of platinum resistant advanced ovarian cancer
26a	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
26b			**In combination with carboplatin and paclitaxel for first-line treatment of adult patients with metastatic squamous NSCLC with PD-L1 expression (Tumor Proportion Score 1-49%) and no EGFR or ALK genomic tumor aberrations**
26c		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

No.	Drug	Designated type of cancer	Designated clinical indications
26d	Pembrolizumab	**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**
26e			*As monotherapy for the treatment of paediatric patients aged 3 years and older with relapsed or refractory cHL who have failed ASCT or following at least two prior therapies when ASCT is not a treatment option*
26f		*Head and neck cancer*	*In combination with platinum and fluorouracil (FU) for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 (CPS >=1) as determined by a validated test*
27	**Polatuzumab Vedotin and Rituximab and Bendamustine**	**Lymphoma**	**For the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant**
28			
29			
30	Sunitinib	Renal cell carcinoma	First line treatment for advanced renal cell carcinoma
31	Trastuzumab	Gastric carcinoma	Combined with Cisplatin & Capecitabine or 5-Fluorouracil (5FU) for HER2 overexpressed metastatic gastric disease (IHC2+ and confirmatory FISH+ result, or IHC3+) in treatment-naive patients 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

Annex 3 to HAB-P335

Drugs Covered by the Ultra-expensive Drugs Programme
(As at end May 2023[1])

Ultra-expensive Drugs

(Items shown in **bold** *are newly introduced in 2022/23 while those shown in italics are newly introduced in 2023/24)*

No.	Drug	Designated clinical indications
1	*Burosumab*	*X-linked hypophosphataemia*
2	Dinutuximab Beta	Treatment of high-risk or relapse/refractory neuroblastoma
3	Eculizumab	Atypical haemolytic uraemic syndrome
4	Nusinersen	Infantile Onset Spinal Muscular Atrophy (SMA) / Childhood Onset SMA / **Pre-symptomatic SMA**
5	*Ravulizumab* [1]	*Paroxysmal Nocturnal Haemoglobinuria (PNH) /* *Atypical haemolytic uraemic syndrome (aHUS)*
6	**Risdiplam**	**Infantile Onset SMA /** **Childhood Onset SMA**
7	Tafamidis Meglumine	For the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment
8	Tafamidis	For treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)
9	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] The exact time for introduction of Ravulizumab to the Ultra-expensive Drugs Programme depends on the availability of this drug in Hong Kong.

Annex 4 to HAB-P335

Medical Devices Covered by the Medical Devices Programme
(As at end May 2023)

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

No.	Medical Devices
1	**Transcatheter Valve Implantation (TVI)** [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**

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

Annex 5 to HAB-P335

Details of new drugs/indications/non-drug items introduced in 2022/23 and 2023/24 (Up to May 2023)

2022/23

(i) New drugs/indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Lorlatinib	New drug/indication	For the treatment of patients with Anaplastic Lymphoma Kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or alectinib or ceritinib or brigatinib as the first ALK inhibitor therapy for metastatic disease	17 Dec 2022
2.	Polatuzumab Vedotin and Rituximab and Bendamustine	New drug/indication	For the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant	17 Dec 2022
3.	Acalabrutinib	New drug/indication	For adult patients with relapsed or refractory mantle cell lymphoma	17 Dec 2022
4.	Neratinib	New drug/indication	For extended adjuvant treatment of adult patients with early-stage hormone receptor (HR)+ve, human epidermal growth factor receptor 2 (HER2)+ve, breast cancer (>1cm or lymph node-positive) and who completed adjuvant trastuzumab-based therapy less than one year ago	17 Dec 2022

- UED Programme

No.	Drug	Change	Indications	Effective Date
1.	Risdiplam	New drug/indication	Infantile Onset Spinal Muscular Atrophy (SMA) / Childhood Onset SMA	17 Dec 2022

(ii) 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
2.	Pembrolizumab	New indication to existing drug	In combination with carboplatin and paclitaxel for first-line treatment of adult patients with metastatic squamous NSCLC with PD-L1 expression (Tumor Proportion Score 1-49%) and no Epidermal growth factor receptor (EGFR) or ALK genomic tumor aberrations	17 Dec 2022
3.	Atezolizumab	New indication to existing drug	As monotherapy for the first-line treatment of adult patients with metastatic NSCLC whose tumours have a PD-L1 expression >=50% tumour cells (TC) and who do not have EGFR mutant or ALK-positive NSCLC	17 Dec 2022
4.	Atezolizumab and Bevacizumab	New indication to existing drug	For the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy	17 Dec 2022

- UED Programme

No.	Drug	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

(iii) New non-drug items / Expansion of indications 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 (TVI)	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

2023/24 (Up to May 2023)

(i) New drugs/indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Daratumumab and Bortezomib	New drug/indication	In combination with thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma (MM) who are eligible for autologous stem cell transplant	26 May 2023
2.	Niraparib	New drug/indication	As monotherapy for the maintenance treatment of adult patients with advanced Homologous Recombination Deficiency (HRd) BRCA wild-type epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response following completion of first-line platinum-based chemotherapy	26 May 2023

- UED Programme

No.	Drugs	Change	Indications	Effective Date
1.	Burosumab	New drug/indication	X-linked hypophosphataemia	26 May 2023
2.	Ravulizumab	New drug/indication	Paroxysmal nocturnal haemoglobinuria (PNH) / Atypical haemolytic uraemic syndrome (aHUS)	Subject to confirmation[1]

(ii) 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 paediatric patients aged 3 years and older with relapsed or refractory cHL who have failed ASCT or following at least two prior therapies when ASCT is not a treatment option	26 May 2023
2.	Pembrolizumab	New indication to existing drug	In combination with platinum and fluorouracil (FU) for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 (CPS >=1) as determined by a validated test	26 May 2023

[1] The exact time for introduction of Ravulizumab to the Ultra-expensive Drugs Programme depends on the availability of this drug in Hong Kong.

Annex 6 to HAB-P335

Chronology of Re-positioning of Items from Community Care Fund (CCF) Medical Assistance Programme to Samaritan Fund & Special Drugs of Hospital Authority (HA) Drug Formulary (As at May 2023)

- *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
14.	Abiraterone # for Prostate Cancer	Dec 2022
15.	Enzalutamide for Prostate Cancer	Dec 2022
16.	Obinutuzumab for CLL	Dec 2022
17.	Axitinib for Renal Cell Carcinoma	Dec 2022
18.	Ceritinib for NSCLC	Dec 2022
19.	Nivolumab ^ for Skin Cancer	May 2023
20.	Dabrafenib and Trametinib * for Skin Cancer	May 2023
21.	Palbociclib for Breast Cancer	May 2023
22.	Ribociclib for Breast Cancer	May 2023
23.	Everolimus for Breast Cancer	May 2023
24.	Trastuzumab emtansine (T-DM1) for Breast Cancer	May 2023
25.	Brentuximab Vedotin for Lymphoma	May 2023

~ Sunitinib is still under CCF for other indication of renal cell carcinoma.

Osimertinib and Abiraterone are still under CCF for other indication – first-line treatment.

^ Nivolumab is still under CCF for other indications of skin cancer, lung cancer and head and neck cancer.

* Dabrafenib and Trametinib are still under CCF for other indication of skin cancer.

- *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-P335

Details of relaxation/revision of clinical guidelines in 2022/23 and 2023/24 (Up to May 2023)

(i) 2022/23

- 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
2.	Abiraterone	For the treatment of adult men with metastatic castration resistant prostate cancer (mCRPC) who are unsuitable for Docetaxel treatment on the basis of predicted intolerance to Docetaxel	Modifications of the clinical guidelines were made due to repositioning of Enzalutamide for the same indication from CCF First Phase Programme to SF.	17 Dec 2022

(ii) 2023/24 (Up to May 2023)

- First Phase Programme

No.	Drugs	Indications	Revision	Effective Date
1.	Trastuzumab	Combined with Cisplatin & Capecitabine or 5-Fluorouracil (5FU) for HER2 overexpressed metastatic gastric disease (IHC2+ and confirmatory FISH+ result, or IHC3+) in treatment-naive patients for their metastatic disease	Update of prescribing and dispensing of the drug with the following due to repositioning of Trastuzumab biosimilars (Herzuma®, Kanjinti®) from CCF First Phase Programme to Special Drugs of HA Drug Formulary: • New patients are recommended to use the biosimilar of Trastuzumab (Herzuma® / Kanjinti®) under Special Drugs of HADF. CCF	7 April 2023

No.	Drugs	Indications	Revision	Effective Date
			will support Trastuzumab (Herceptin®) only for those patients continuing their treatment of Trastuzumab (Herceptin®) under CCF support for the current indication.	
2.	Abemaciclib	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	Modifications of the clinical guidelines were made due to repositioning of Palbociclib and Ribociclib for the same indication from CCF First Phase Programme to SF, with the clause *"(endocrine therapy for patient renewing her application with the initial application created before 11 January 2020)"* removed for the exclusion criterion *"Prior systemic therapy for the locally advanced / metastatic breast cancer"*.	26 May 2023

- UED Programme

No.	Drug	Indication	Revision	Effective Date
1.	Dinutuximab Beta	Treatment of high-risk or relapse/refractory neuroblastoma	Inclusion criteria or eligibility extended to patients of relapsed or refractory neuroblastoma with soft tissue with or without bone and/or bone marrow involvement.	26 May 2023

Annex 8 to HAB-P335

Administrative cost budget for 2023/24
of the three Community Care Fund Medical Assistance Programmes

Programmes / Budget	First Phase Programme ($ million)	UED Programme ($ million)	MD Programme ($ million)	Total ($ million)
Staff cost	26.60	7.70	1.46	35.76
Computer system	2.00[1]	-	-	2.00
Audit fee[2]	-	-	-	-
Others	1.33	0.96	0.18	2.47
Contingency	3.32	0.96	0.18	4.46
Total	**33.25**	**9.62**	**1.82**	**44.69**

[1] The budget has included the estimated expenditure of computer system for the three Medical Assistance Programmes.
[2] The existing auditor provides free audit services for the three Medical Assistance Programmes.