醫院管理局大會
文件第 311 號

2021 年 6 月 24 日醫院管理局大會參考文件
關愛基金醫療援助項目週年運作報告

徵詢意見

請成員備悉醫院管理局（醫管局）在食物及衞生局（食衞局）監督下負責執行的關愛基金（基金）醫療援助項目於2020/21年度的週年運作報告[1]。有關基金醫療援助項目涵蓋的藥物／適應症／醫療裝置之建議已於相關管治平台討論並獲支持，並已按情況向醫療服務發展委員會（醫務發展委員會）匯報[2]。

背景

2. 基金自2011年成立以來，先後就醫療、教育、福利、民政及房屋範疇推出不同的援助項目。醫管局在食衞局的監督下負責執行三個醫療援助項目，包括：

(a) 基金醫療援助項目（首階段計劃）（首階段計劃）；

(b) 資助合資格病人購買價錢極度昂貴的藥物（包括用以治療不常見疾病的藥物）（極度昂貴藥物計劃）；及

(c) 資助合資格的公立醫院病人購買指定的用於介入程序及在體內設置的醫療裝置（醫療裝置計劃）。

計劃旨在資助有需要而合資格的病人購買特定自費癌症藥物、極度昂貴藥物及指定的用於介入程序及在體內設置的醫療裝置。基金醫療援助項目的背景及管治資料，以及三個項目由2021年5月起的涵蓋範圍分別載於**附件1-4**。

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[1] 上一份基金援助項目週年運作報告（2019/20 年度）於 2020 年 6 月 18 日提呈醫管局大會（醫管局大會文件第 301 號）。

[2] 於 2020 年 4 月 16 日傳閱的醫務發展委員會文件第 601 號「由 2020 年第二或第三季起引入撒瑪利亞基金及關愛基金醫療援助項目涵蓋範圍的新藥物／適應症簡介」；於 2020 年 10 月 12 日討論的醫務發展委員會文件第 610 號「由 2020 年第四季起引入撒瑪利亞基金及關愛基金醫療援助項目涵蓋範圍的新藥物／適應症及復康用品簡介」；及於 2021 年 4 月 23 日討論的醫務發展委員會文件第 629 號「由 2021 年第二季起引入撒瑪利亞基金及關愛基金醫療援助項目涵蓋範圍的新藥物／適應症簡介」。

涵蓋範圍及申請統計數字

2020/21 及 2021/22 年度涵蓋範圍之變更

3. 因應治療方案的科學證據、成本效益及科技進展的變化，以及服務的持續發展，醫管局密切留意最新醫學發展，以便按既定機制為各項計劃引入適合的藥物或項目。

4. 為加快於基金醫療援助項目引入新藥／醫療裝置，由政務司司長主持的扶貧委員會於 2019 年 10 月通過簡化三個基金醫療援助項目引入新藥／醫療裝置的審批程序，由 2020/21 年度起生效。按照簡化後的安排，在扶貧委員會為各醫療援助項目批核一個年度指標性預算下，授權基金專責小組主席，即勞工及福利局局長，為建議納入的新藥物及醫療裝置作最終批核。

5. 截至 2020 年 3 月 31 日，首階段計劃及極度昂貴藥物計劃分別涵蓋 24 種自費癌症藥物及三種極度昂貴藥物，而醫療裝置計劃涵蓋六種醫療裝置。在醫管局關愛基金行政委員會支持下，並獲關愛基金有關當局批准，三個項目於 2020/21 及 2021/22 年度涵蓋範圍之變更概列如下：

計劃		**2020/21年度涵蓋範圍之變更[3]**	**2021/22年度之變更[4]** *(截至2021年5月)*
首階段計劃	**新增藥物**	- 10 種藥物	- 一種藥物
	新增或放寬適應症	- 三種適應症	- 兩種適應症
	藥物改納入撒瑪利亞基金涵蓋範圍	- 一種藥物	沒有
極度昂貴藥物計劃	**新增藥物**	- 一種藥物	- 一種藥物
	藥物 / 適應症改納入撒瑪利亞基金涵蓋範圍	- 一種藥物 / 適應症 *(依庫珠單抗用於治療陣發性夜間血紅素尿症)*[5]	沒有
醫療裝置計劃	**擴闊適應症範圍**	沒有	- 一種適應症

[3] 已向醫務發展委員會匯報（醫務發展委員會文件第 601 及 610 號）。

[4] 已向醫務發展委員會匯報（醫務發展委員會文件第 629 號）。

[5] 有關藥物／適應症改納入撒瑪利亞基金涵蓋範圍於 2020 年 4 月獲醫務發展委員會批准（醫務發展委員會文件第 601 號）。已獲批的關愛基金病人個案將繼續在關愛基金援助下接受治療，直至獲批療程完結或停止治療為止。如病人需要繼續治療，有關個案將由撒瑪利亞基金續批。換言之，在藥物 / 適應症改納入撒瑪利亞基金涵蓋範圍後批核的新個案或續批個案，會改由撒瑪利亞基金資助。此項藥物／適應症獲納入撒瑪利亞基金後，極度昂貴藥物計劃下所定的病人費用分擔上限 100 萬元及病人身分規定（即屬香港永久性居民）維持不變。

6. 上述新增藥物 / 適應症的詳情載於**附件5**。基金醫療援助項目改納入撒瑪利亞基金及醫管局藥物名冊專用藥物的時序表載於**附件6**。除納入新藥物及適應症外，多種涵蓋藥物的臨床指引亦獲放寬或修訂，詳情載於**附件7**。

7. 截至2021年3月31日，首階段計劃及極度昂貴藥物計劃分別涵蓋33種自費癌症藥物及四種極度昂貴藥物，醫療裝置計劃則涵蓋六種醫療裝置。隨著2021年5月下旬對2021/22年度涵蓋範圍所作的變更，首階段計劃現時涵蓋 **34種自費藥物**。極度昂貴藥物計劃方面，計及2021年4月引入名為替沙侖賽(Tisagenlecleucel)的新藥物後，此計劃現時涵蓋**五種極度昂貴藥物**。至於醫療裝置計劃，隨著2021年5月下旬就經皮導管肺動脈瓣植入術落實擴闊及修訂臨床適應症範圍，計劃現時涵蓋**六種介入性醫療裝置**。

獲批申請及批出資助金額

8. 於2020/21財政年度（2020年4月1日至2021年3月31日），三個基金醫療援助項目的獲批申請宗數、批出資助總額及每宗申請平均批出資助金額概列如下：

計劃	**獲批申請宗數**	**批出資助總額** **（百萬元）**	**每宗申請平均批出資助金額（元）**
首階段計劃	2 869	642.59	223,977
極度昂貴藥物計劃	31	77.21	2,490,519
醫療裝置計劃	118	29.07	246,374

首階段計劃涉及資助額最多之藥物

9. 首階段計劃2020/21年度涉及資助額最多之藥物是用於治療肺癌的奧希替尼(Osimertinib)、用於治療肺癌的匹博利組單抗(Pembrolizumab)，以及治療乳癌的培妥珠單抗(Pertuzumab)。於2020/21年度，就這些藥物／適應症批出的資助總額共3億1,550萬元，佔藥物申請批出的資助總額49%；每宗申請平均批出資助金額約390,468元。

財政狀況

三個醫療援助項目 2020/21 年度經審計的財務報表

10. 三個基金醫療援助項目截至2021年3月31日止年度的經審計財務報表載於醫管局內務大會文件第1666號「關愛基金醫療援助項目2020/21年度經審計財務報表」，以供成員審批。

三個醫療援助項目 2021/22 年度指標性預算

11. 根據上文第4段所述的簡化審批程序，三個項目2021/22年度的指標性資

助批核預算及行政開支預算分別於2020年11月及12月獲基金專責小組及扶貧委員會支持及批准，摘錄如下：

計劃 / 預算	首階段計劃 （百萬元）	極度昂貴藥物計劃 （百萬元）	醫療裝置計劃 （百萬元）	總金額 （百萬元）
指標性資助批核預算	1,379.00	303.00	50.00	1,732.00
行政開支預算[6] *（各項計劃的行政開支預算分目載於**附件8**）*	68.95	15.15	2.50	86.60

經濟審查機制優化措施

12. 一如2020年6月向醫管局大會所作的匯報（醫管局大會文件第301號），政府及醫管局於2019年初就基金醫療援助項目的經濟審查機制實施了以下優化措施[7]：

(a) 修訂藥物資助申請中每年可動用財務資源的計算方法，以扣減病人家庭資產淨值的 50%；以及

(b) 修訂經濟審查時所採取「家庭」[8]的定義，只計算與病人有財政聯繫的核心家庭成員。

13. 醫管局分析了優化措施實施前後的藥物申請統計數字。總括而言，優化措施取得正面成果，所得主要觀察如下：

(a) 獲批申請宗數增加；
(b) 獲批資助金額增加；
(c) 病人分擔費用減少；及
(d) 一至二人家庭獲批申請個案百分比增加。

14. 下表載列2019年2月16日(優化措施實施首日)[9] 至2020年2月15日期間與2018-19 年度同期的藥物資助申請數字的比較。實際統計數字與2018年11月向立法會衞生事務委員會提供的原來估計 / 假設相若：

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[6] 包括人手開支、審計費用及其他行政開支，上限為指標性資助批核預算及該年度額外資助預算（如有）的 5%。

[7] 關愛基金醫療援助計劃的相關優化措施於 2019 年 1 月獲扶貧委員會通過；撒瑪利亞基金的相關優化措施於 2018 年 11 月 22 日於醫管局大會會議上討論及通過 (醫管局大會內務會議文件第 1432 號)。

[8] 優化措施實施前，「家庭」的定義為病人及同住的核心家庭成員，即病人的配偶、子女、父母和屬受養人的兄弟姊妹。

[9] 優化措施由 2019 年 2 月 16 日起適用於撒瑪利亞基金和關愛基金首階段計劃及關愛基金醫療裝置計劃的申請。鑑於關愛基金極度昂貴藥物計劃所涵蓋的藥物費用相對高昂，加上病人數目不多，優化措施在 2019 年 1 月起已適用於該計劃的新申請個案。

		估計 / 假設 (*2018 年 11 月向衞生事務委員會提供*)	**實際統計數字** (*2019 年 2 月 16 日 - 2020 年 2 月 15 日期間與 2018-19 年度同期比較*)
所有申請	獲批申請宗數增加	-	32%
	獲批資助金額增加	40%	63%
非綜合社會保障援助（綜援）受助人的申請	獲批申請宗數增加	30%	39%
	獲批資助金額增加	-	71%
	病人分擔費用減少的現有申請個案	每年~1 005 宗	~1 400 宗[10]
	病人分擔費用平均減少金額	~30,000 元	~31,100 元
一至二人家庭藥物申請個案百分比**增加 28%** (由 60% 增至 88%)			

* *以上統計數字已計入 2018 年 2 月後引入新資助項目的影響。*

15. 非綜援受助人的申請數目增加了39%。我們仔細審視有關增幅後，察悉優化措施令65歲以上受助人百分比增加，並使受惠群組擴展至資產水平相對較高的病人。這很可能是由於因為修訂了每年可動用財務資源的計算方法，扣減資產淨值的50%，讓資產相對較多的病人符合資格申請資助。

16. 簡而言之，這些優化措施擴闊了撒瑪利亞基金及關愛基金醫療援助項目藥物資助的涵蓋範圍，令 (a) 個別病人的分擔費用減少；及 (b) 涵蓋更多以往未能受惠的組別。

進一步改良經濟審查機制

17. 經檢討於2019年初實施的優化措施的成效，並考慮持份者的意見及與其他公共援助計劃保持一致，藥物資助的經濟審查機制於2021年4月下旬作進一步改良(於2021年3月獲扶貧委員會通過)，以減輕需長期服藥病人的經濟負擔，具體措施包括：

(i) 就**持續申請個案**而言，修訂每年可動用財務資源的計算方法，把病人已支付上一個療程的藥費開支[11] 納入為病人家庭可動用收入的認可扣減項目[12]，以扣除有關開支，並只計算病人家庭可動用收入的80%[13] ；

[10] 在實施日期前獲批申請並在該日期後獲處方受資助藥物而獲額外資助的個案亦已包括在內。就這些個案，醫管局計算病人的每年可動用財務資源時，按比例扣減病人家庭資產淨值的 50%，以計算經修訂的病人分擔費用。

[11] 過去 12 個月在公立醫院／診所就醫時就現正申請資助的藥物所支付的藥費。

[12] 在改良措施實施前，過去 12 個月在公立醫院／診所就醫的醫療費用(不包括已獲撒瑪利亞基金和關愛基金醫療援助項目資助的藥費，以及現正申請資助的藥費)已列入認可扣減項目。

[13] 如「家庭每月總收入」與「每月認可扣減項目」相減後的差額為正數才會採用 20%的扣減比率。

(ii) 就**所有藥物資助申請**，在計算每年可動用財務資源時，納入更多認可扣減項目(25 歲或以下修讀大專課程的全日制學生學費[14] 及贍養費開支)，並調整收入的計算方法[15] ；及

(iii) 延長持續藥物資助申請人的經濟審查有效期[16]。

18. 政府與醫管局會繼續適時探討進一步加強財政資助的可持續性及申請便捷度。

質素保證

臨床審核

19. 醫管局引入臨床審核，以確保醫生所作的基金援助轉介符合當時臨床指引的準則。因應過往一年的已批核個案數目及批出資助金額，選取了用以治療大腸直腸癌的貝伐珠單抗(Bevacizumab)及經導管微創主動脈瓣植入術之獲批申請進行臨床審核。

20. 就2019年4月1日至2020年3月31日期間獲批的貝伐珠單抗(Bevacizumab)申請個案，相關專科醫生組成的臨床審核小組對21宗[17] 抽選個案進行同儕審核，結果認為當中19宗個案(90%)完全符合當時的臨床指引[18]。

21. 就2019年4月1日至2020年3月31日期間獲批的經導管微創主動脈瓣植入術的申請個案，相關專科醫生組成的臨床審核小組對六宗抽選個案進行同儕審核，認為所有抽選個案符合當時的臨床指引。

22. 審核報告會發給相關統籌委員會傳閱，並會向醫管局關愛基金行政委員會匯報。

經濟審查審核

23. 為確保醫務社會服務部對基金申請個案的經濟審查符合既定指引，並適時提出改善建議，醫管局引入了經濟審查審核。

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[14] 在改良措施實施前，就讀中學或以下級別的 21 歲以下子女過去六個月的學費已列入認可扣減項目之一。

[15] 雙糧、年終酬金、花紅及酬金，以及安老按揭／保單逆按每月發放的款項不會列入為收入計算。

[16] 在病人分擔費用不超出 2,000 元的情況下，其首次申請的經濟審查有效期由 12 個月延長至 18 個月。符合上述條件的病人在續期申請時，無須接受經濟審查，繼續支付原有需分擔費用。此外，假如病人在首次申請後的一至兩個月內獲轉介第二次申請，醫管局會豁免其提交財務文件的規定。倘若病人因家庭經濟狀況有變而需要重新進行經濟審查，可在申請期內隨時提出相關要求。

[17] 符合抽選藥物獲批個案 5%的目標。

[18] 根據基金臨床指引，其中一個終止治療準則是「病人在接受貝伐珠單抗治療期間疾病惡化」。在 21 宗抽選個案中，有兩宗個案病人在治療期間病情惡化，但仍繼續接受貝伐珠單抗治療，因此認為此兩宗個案沒有完全遵照臨床指引。

24. 就2020年1月1日至2020年12月31日期間獲批之申請，不同醫院醫務社會服務部的行政助理在醫管局總辦事處職員提供適切的協助下，抽選了113宗基金申請個案[19] 以進行同儕審核。有關審核於2020年第二季至2021年第一季期間分三批開展。視乎情況，審核結果會向不同管治平台匯報，包括醫管局關愛基金行政委員會及醫務社會服務部聯繫會議。

已批核個案之覆核

25. 為保證公帑用得其所，基金醫療援助項目設有批核後覆核機制，以預防和偵查醫療援助計劃的詐騙和濫用。就2019/20及2020/21年度獲批之申請，共抽選了2 551宗個案[20] 由聯網覆核組進行覆核。有關基金醫療援助項目已批核個案的覆核結果，將於2021年第四季連同撒瑪利亞基金及醫療費用減免的已批核個案覆核結果一併向醫管局大會匯報。

基金的宣傳推廣

26. 為加強推廣首階段計劃、極度昂貴藥物計劃及醫療裝置計劃，醫管局每月於網站上載有關申請統計數字，例如累計批核申請宗數及資助金額等，此外亦安排了對內及對外的宣傳措施。對內方面，醫管局適時向前線員工發布有關指引及文件；對外宣傳則包括於病人通訊刊登文章、透過醫管局網站上的基金網頁提供最新資訊、利用醫管局「智友站」平台加強推廣、舉辦病人論壇，以及於醫管局轄下醫院和診所派發單張等。

醫院管理局
HAB\PAPER\311
2021 年 6 月 17 日

[19] 符合抽選已獲批及涉及較大資助金額（即 10 萬元或以上）非綜援個案 2%的目標。

[20] 符合抽選已獲批高、中、低風險非綜援個案分別 100%、15%-25%及 5-10%的目標。高、中、低風險個案的相應資助額分別為：30 萬元或以上、高於 10 萬元但低於 30 萬元，以及 10 萬元以下。

Annex 1 to HAB-P311

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

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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 third term CoP has commenced on 1 July 2018. Two Task Forces have been set up under the third 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.

(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.

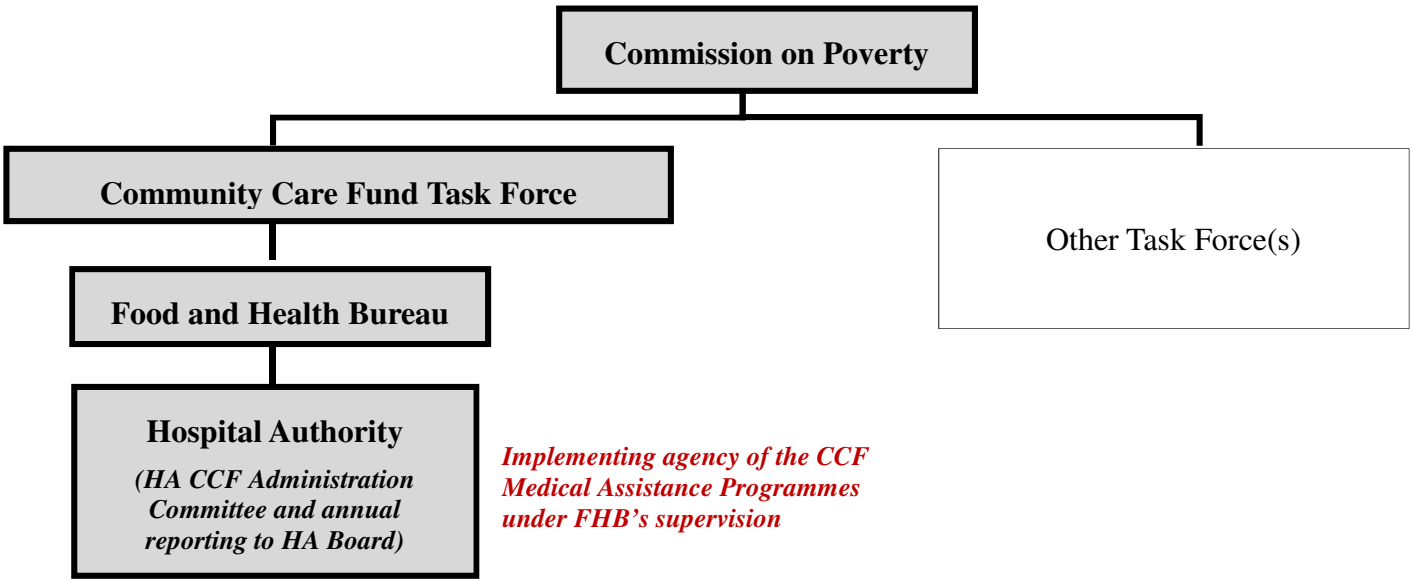
(c) **Subsidy for Eligible Patients of HA to Purchase Specified Implantable Medical Devices for Interventional Procedures (MD Programme)** was introduced on 1 August 2017. It provides financial assistance to needy HA patients to have early access to specified implantable medical devices for interventional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

↓

HA's Drug Management Committee and **Medical Device Advisory Committee** recommend suitable drugs and medical devices respectively for inclusion into the Programmes' coverage (twice a year)

↓

The HA CCF Administration Committee considers the recommended new drugs and medical devices

↓

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

↓

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

↓

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-P311

Drugs Covered by the First Phase Programme
(As at May 2021)

Self-financed drugs :
(Items shown in **bold** *are newly introduced in 2020/21 while those shown in italics are newly introduced in 2021/22)*

No.	Drug	Clinical indications
1	**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**
2a	Abiraterone	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	Alectinib	For the treatment of patients with Anaplastic Lymphoma Kinase (ALK)+ve, metastatic non-small cell lung cancer (NSCLC) who have progressed on Crizotinib and intolerant to Ceritinib, or who have central nervous system (CNS)-progression after Crizotinib
4	**Atezolizumab**	**For Epidermal growth factor receptor (EGFR)-ve and ALK-ve NSCLC progressed on or following platinum-based chemotherapy**
5	Axitinib	For patients with advanced renal cell carcinoma (RCC), whose disease has progressed on or after first-line treatment
6	Bendamustine	Treatment of Chronic Lymphocytic Leukaemia (CLL) in patients who are unable to tolerate Fludarabine-based chemotherapy OR are refractory to Fludarabine i.e. not responded to Fludarabine or relapsed within 12 months of treatment
7a	Bevacizumab	First line treatment of RAS mutant metastatic colorectal cancer in combination with chemotherapy in patients indicated for intensive treatment OR First-line treatment of RAS wild type metastatic colorectal cancer in combination with chemotherapy in patients indicated for intensive treatment who are unsuitable for or intolerant to Cetuximab / Panitumumab
7b		With carboplatin and paclitaxel for front-line advanced epithelial ovarian / fallopian tube / primary peritoneal cancer
8a	**Brentuximab Vedotin**	**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**

No.	Drug	Clinical indications
8b		**For the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma**
8c		**For the treatment of adult patients with CD30+ cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy**
9	**Brigatinib**	**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**
10	Ceritinib	For adult patients with ALK+ve advanced NSCLC previously treated with Crizotinib
11	Dabrafenib	Combination of dabrafenib and trametinib for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma
12	Trametinib	
13	**Durvalumab**	**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**
14a	Enzalutamide	For mCRPC progressed on or after docetaxel-based chemotherapy regimen
14b		For the treatment of adult men with mCRPC who are unsuitable for Docetaxel treatment on the basis of predicted intolerance to Docetaxel
15	Everolimus	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
16	**Inotuzumab Ozogamicin**	**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 TKI treatment**
17	**Ixazomib**	**In combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy**
18	**Lenalidomide**	
19	Lapatinib	HER2+ve advanced breast cancer with prior therapy including an anthracycline, a taxane, and Trastuzumab
20	**Lenvatinib**	**For first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)**
21a	Nivolumab	As monotherapy for BRAF V600 wild-type unresectable or metastatic melanoma
21b		**For adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection**
21c		**For EGFR-ve and ALK-ve NSCLC progressed on or following platinum-based chemotherapy**

No.	Drug	Clinical indications
22	Obinutuzumab	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*	*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*
24a	Osimertinib	For the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation positive NSCLC who has progressed after previous treatment with an EGFR TKI
24b		*For first line treatment of adult patients with EGFR mutation +ve NSCLC with CNS metastases*
25	Palbociclib	**For treatment of HR+ve HER2-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy**
26	Pazopanib	First line treatment for advanced RCC
27	Pegylated liposomal Doxorubicin	Second-line of platinum refractory or subsequent treatment of platinum resistant advanced ovarian cancer
28a	**Pembrolizumab**	**For first-line treatment for metastatic NSCLC with high PD-L1 expression (Tumor Proportion Score >=50%) with no EGFR or ALK genomic tumor aberrations**
28b		*For 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*
29	Pertuzumab	In combination with trastuzumab and docetaxel (Taxane) in HER2+ve metastatic or locally recurrent unresectable breast cancer patients with no prior anti-HER2 or chemotherapy for their metastatic disease
30	Ribociclib	**For treatment of HR+ve HER2-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy**
31a	Sunitinib	First line treatment for advanced RCC
31b		Unresectable or metastatic gastrointestinal stromal tumour after failure or intolerance to Imatinib
32	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

No.	Drug	Clinical indications
33	Trastuzumab emtansine (T-DM1)	As monotherapy for HER2+ve metastatic breast cancer with prior Trastuzumab and/or taxane therapy for their metastatic disease
34	Vemurafenib	As monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma

Annex 3 to HAB-P311

Drugs Covered by the Ultra-expensive Drugs Programme
(As at May 2021)

Ultra-expensive Drugs
(Items shown in **bold** *are newly introduced in 2020/21 while those shown in italics are newly introduced in 2021/22)*

No.	Drug	Clinical Indication
1.	**Dinutuximab Beta**	**Treatment of high-risk or relapse/refractory neuroblastoma**
2.	Eculizumab	Atypical Haemolytic Uraemic Syndrome (aHUS)
3.	Nusinersen	Infantile Onset Spinal Muscular Atrophy (SMA) / Childhood onset Spinal Muscular Atrophy (SMA)
4.	Tafamidis	Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP)
5.	*Tisagenlecleucel*	*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*

Annex 4 to HAB-P311

Medical Devices Covered by the Medical Devices Programme
(As at May 2021)

Implantable Medical Devices
(Items shown in **bold** *are newly introduced in 2020/21 while those shown in italics are newly introduced in 2021/22)*

No.	Implantable Medical Devices
1.	Transcatheter Aortic Valve Implantation (TAVI)
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.	Valve-in-valve Transcatheter Aortic Valve Implantation (VIV - TAVI)

Annex 5 to HAB-P311

Details of new drugs/indications/non-drug items introduced in 2020/21 and 2021/22 (Up to May 2021)

2020/21

(i) New drugs/indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1	Brentuximab Vedotin	New drug	- 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 - For the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma - For the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma	23 May 2020
2	Brigatinib	New drug	For the treatment of patients with ALK+ve, metastatic non-small cell lung cancer (NSCLC) who have progressed on Crizotinib and intolerant to Ceritinib, or who have central nervous system (CNS)-progression after Crizotinib	23 May 2020
3	Durvalumab	New drug	For unresectable, stage III non-small cell lung cancer (NSCLC) with at least 1% of tumour cells expressing PD-L1, whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy	23 May 2020
4	Lenvatinib	New drug	For first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)	23 May 2020
5	Ixazomib	New drug	In combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy	23 May 2020
6	Lenalidomide	New drug		23 May 2020

No.	Drugs	Change	Indications	Effective Date
7	Pembrolizumab	New drug	For first-line treatment for metastatic non-small cell lung cancer (NSCLC) with high PD-L1 expression (Tumor Proportion Score >=50%) with no EGFR or ALK genomic tumor aberrations	23 May 2020
8	Abemaciclib	New drug	For treatment of HR+ve HER2-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy	29 December 2020
9	Atezolizumab	New drug/indication	For EGFR-ve and ALK-ve metastatic non-small cell lung cancer (NSCLC) progressed on or following platinum-based chemotherapy	29 December 2020
10	Inotuzumab Ozogamicin	New drug/indication	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 TKI treatment	29 December 2020

- UED Programme

No.	Drugs	Change	Indications	Effective Date
1	Dinutuximab Beta	New drug	Treatment of high-risk or relapse/refractory neuroblastoma	29 Dec 2020

(ii) Re-positioning from Community Care Fund Medical Assistance Programme to Samaritan Fund

- *Re-positioning from First Phase Programme to Samaritan Fund*

No.	Drug	Indication	Effective Date
1	Sorafenib	Hepatocellular carcinoma (HCC) : ineligible for resection, transplant or loco-regional therapy	29 Dec 2020

- *Re-positioning from UED Programme to Samaritan Fund*

No.	Drug	Indication	Effective Date
1	Eculizumab	Paroxysmal Nocturnal Haemoglobinuria (PNH)	11 July 2020

(iii) New or relaxed indications

No.	Drugs	Change	Indications	Effective Date
1	Palbociclib	Relaxation of indication	For treatment of HR+ve HER2-ve locally advanced or metastatic breast cancer in combination with an aromatase inhibitor, as initial endocrine therapy	23 May 2020
2	Ribociclib			
3	Nivolumab	New indication to existing drug	For adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection	29 Dec 2020
			For EGFR-ve and ALK-ve metastatic non-small cell lung cancer (NSCLC) progressed on or following platinum-based chemotherapy	

2021/22 (Up to May 2021)

(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

- 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

(ii) New or relaxed indications

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

(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	Post-operative dysfunctional right ventricular outflow tract	22 May 2021

Annex 6 to HAB-P311

Chronology of Re-positioning of Items from Community Care Fund Medical Assistance Programme to Samaritan Fund & Special Drugs of HA Drug Formulary

- *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) - 1st line treatment	Feb 2019
5.	Erlotinib for NSCLC - 1st line treatment	Feb 2019
6.	Gefitinib for NSCLC - 1st line treatment	Feb 2019
7.	Sorafenib for Liver Cancer	Dec 2020

- *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

- *To Samaritan Fund*

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

Annex 7 to HAB-P311

Details of relaxation/revision of clinical guidelines in 2020/21 and 2021/22 (Up to May 2021)

(i) 2020/21

- First Phase Programme

No.	Drugs/items	Indication	Revision	Effective Date
1	Bendamustine	Treatment of Chronic Lymphocytic Leukaemia (CLL) in patients who are unable to tolerate Fludarabine-based chemotherapy OR are refractory to Fludarabine i.e. not responded to Fludarabine or relapsed within 12 months of treatment	To include new formulation Rituximab Subcutaneous (SC) Injection 1600mg	10 April 2020
2	Palbociclib / Ribociclib	In combination with an aromatase inhibitor as initial endocrine based therapy for the treatment of HR+ve, HER2-ve locally advanced or metastatic breast cancer in postmenopausal patients *(Previous indication before relaxation of clinical guidelines)*	Add remark for one of the exclusion criteria for clarity. "Prior systemic therapy* for the locally advanced / metastatic breast cancer *(*endocrine therapy for patient renewing her application with the initial applications created before 11 January 2020)"*	10 April 2020
3	Pertuzumab	In combination with trastuzumab and docetaxel (Taxane) in HER2+ve metastatic or locally recurrent unresectable breast cancer patients with no prior anti-HER2 or chemotherapy for their metastatic disease	Change of Cap Ceiling from 27 cycles to 28 vials *(Apply to patients who have not reached the previous cap ceiling (27 cycles) as at 11 July 2020)*	31 July 2020

No.	Drugs/items	Indication	Revision	Effective Date
4	Bendamustine	Treatment of Chronic Lymphocytic Leukaemia (CLL) in patients who are unable to tolerate Fludarabine-based chemotherapy OR are refractory to Fludarabine i.e. not responded to Fludarabine or relapsed within 12 months of treatment	Inclusion of biosimilars of Rituximab (Rixathon® and Truxima®)	22 August 2020
5	Pertuzumab	In combination with trastuzumab and docetaxel (Taxane) in HER2+ve metastatic or locally recurrent unresectable breast cancer patients with no prior anti-HER2 or chemotherapy for their metastatic disease	To generalize the recommended dosage of Trastuzumab as SC Trastuzumab will also be provided for free by drug company	10 October 2020
6	Ixazomib and Lenalidomide	In combination with dexamethasone for the treatment of multiple myeloma in patients who have received at least one prior therapy	Revision of the "Exclusion Criteria"	29 December 2020
7	Nivolumab	Monotherapy for BRAF V600 Wild-type Unresectable or Metastatic Melanoma	Add " iv) Patients with prior adjuvant Nivolumab therapy" under section of "Exclusion Criteria", taken into account the introduction of new indication for melanoma as mentioned in paragraph 3a(iii)	29 December 2020

- UED Programme

No.	Drugs/items	Indication	Revision	Effective Date
1	Nusinersen	Infantile- / Childhood-onset Spinal Muscular Atrophy	Refinement and clarification of age limit for commencement of treatment under "Inclusion Criteria or Eligibility", and details under "Monitoring / Treatment and Reassessment" were made	29 December 2020
2	Dinutuximab Beta	Treatment of high-risk or relapse/refractory neuroblastoma	Updated the treatment criteria by revising the "Exclusion Criteria": - refinement of point 4 *"Patients who relapse with soft tissue mass and previously already received anti-GD2 treatment (includes Dinutuximab Beta)"*; and - addition of point 6 *"Pregnancy"*	3 February 2021

(ii) 2021/22 (Up to May 2021)

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	Inclusion of biosimilars of Trastuzumab (Herzuma® and Kanjinti®)	10 April 2021

No.	Drugs	Indications	Revision	Effective Date
		for their metastatic disease		
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 "Previous Treatment"	10 April 2021

Annex 8 to HAB-P311

Administrative cost budget for 2021/22 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	58.60	12.87	2.12	73.59
Computer system	2.00	-	-	2.00
Audit fee	0.20	0.10	0.10	0.40
Others	1.26	0.67	0.03	1.96
Contingency	6.89	1.51	0.25	8.65
Total	**68.95**	**15.15**	**2.50**	**86.60**