醫院管理局大會
文件第 365 號

2025 年 6 月 26 日醫院管理局大會參考文件
關愛基金醫療援助項目周年運作報告

徵詢意見

請成員備悉醫院管理局（**醫管局**）在醫務衞生局（**醫衞局**）監督下負責執行的關愛基金（**基金**）醫療援助項目於 2024/25 年度的周年運作報告[1]。有關基金醫療援助項目涵蓋的藥物／適應症／醫療裝置之建議已獲相關管治平台支持，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. 基金是於2011年初根據《民政事務局局長法團條例》（現稱《民政及青年事務局局長法團條例》）（第1044章）成立的信託基金，信託人是民政事務局局長法團（現稱民政及青年事務局局長法團）。基金成立的主要目的，是為經濟上有困難的市民提供援助，特別是那些未被納入社會安全網，或雖然身處安全網但有一些特殊需要未獲得照顧的人。此外，基金也可考慮推行先導計劃，協助政府研究有哪些措施可考慮納入其常規的資助及服務範圍。政府自2012年12月重設扶貧委員會後，基金由2013年起納入扶貧委員會的工作範圍內。委員會下設關愛基金專責小組，負責統籌和監察基金醫療援助項目的推行、構思新計劃，以及在適當時向委員會匯報其工作計劃和進展。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。醫管局在醫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**）。

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[1] 上一份基金援助項目周年運作報告（2023/24 年度）於 2024 年 6 月 27 日提呈醫管局大會（醫管局大會文件第 347 號）。

[2] 於 2024 年 4 月 26 日討論的醫務發展委員會文件第 728 號「由 2024 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／適應症及非藥物項目簡介」；於 2024 年 10 月 21 日討論的醫務發展委員會文件第 743 號「由 2024 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／適應症簡介」；及於 2025 年 4 月 7 日討論的醫務發展委員會文件第 762 號「由 2025 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／適應症及非藥物項目簡介」。

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，以及三個項目自2025年5月底生效的涵蓋範圍分別載於**附件1–4**。

涵蓋範圍及申請統計數字

2024/25 及 2025/26 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、治療選擇及服務技術進展的變化，醫管局會繼續緊隨最新醫學發展，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，扶貧委員會於2019年10月通過由2020/21年度起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。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為建議納入的新藥物及醫療裝置作最終批核。

5. 截至2024年3月31日，首階段計劃及極度昂貴藥物計劃分別涵蓋32種自費癌症藥物及10種極度昂貴藥物，而醫療裝置計劃則涵蓋六種醫療裝置。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2024/25及2025/26年度（截至2025年5月底）涵蓋範圍之變更概列如下：

計劃		**2024/25年度之變更[3]**	**2025/26年度之變更[4]** *（截至2025年5月底）*
首階段計劃	**新增藥物**	- 兩種藥物 *（治療神經纖維瘤病的司美替尼(Selumetinib)；及治療淋巴癌的扎奴替尼(Zanubrutinib)）*	- 兩種藥物 *（治療乳癌的阿貝西利(Abemaciclib)；及治療多發性骨髓瘤的塞利尼索(Selinexor)）*
	新增或放寬適應症	- 七種適應症 *（達雷木單抗與來那度胺(Daratumumab in combination with Lenalidomide)；侖伐替尼與匹博利組單抗(Lenvatinib in combination with Pembrolizumab)；奧希替尼(Osimertinib)；維泊妥組單抗與利妥昔單抗(Polatuzumab Vedotin in combination with Rituximab)；阿替利組單抗(Atezolizumab)；伊布替尼(Ibrutinib)；及匹博利組單抗(Pembrolizumab)）*	- 一種適應症 *（匹博利組單抗(Pembrolizumab)）*

[3] 已向醫務發展委員會匯報（醫務發展委員會文件第 728 及 743 號）。

[4] 已向醫務發展委員會匯報（醫務發展委員會文件第 762 號）。

計劃		**2024/25年度之變更[3]**	**2025/26年度之變更[4]** *（截至2025年5月底）*
	藥物改納入撒瑪利亞基金涵蓋範圍	- 九種適應症 *（治療前列腺癌的阿比特龍(Abiraterone)；治療卵巢上皮癌、輸卵管癌和原發性腹膜癌的貝伐珠單抗(Bevacizumab)[5]與奧拉帕利(Olaparib)；治療肺癌的奧希替尼(Osimertinib)[6]；治療膀胱癌的匹博利組單抗(Pembrolizumab)[7]；治療皮膚癌的達拉非尼與曲莫替尼(Dabrafenib in combination with Trametinib)；治療白血病的奧加米星吉妥組單抗(Gemtuzumab Ozogamicin)；治療頭頸癌的尼伏人單抗(Nivolumab)[8]；及治療腎細胞癌的尼伏人單抗與伊匹木單抗(Nivolumab in combination with Ipilimumab)[9]）*	- 10種適應症 *（治療肝細胞癌的阿替利組單抗(Atezolizumab)[10]及貝伐珠單抗(Bevacizumab)[5]；治療大腸直腸癌的貝伐珠單抗(Bevacizumab)[5]；治療多發性骨髓瘤的伊沙佐米(Ixazomib)與來那度胺(Lenalidomide)[11]；治療乳癌的拉帕替尼(Lapatinib)；治療肺癌的洛拉替尼(Lorlatinib)；治療卵巢癌的鹽酸多柔比星脂質體(Pegylated Liposomal Doxorubicin)；治療肺癌及淋巴癌的匹博利組單抗(Pembrolizumab)[7]；治療腎細胞癌的舒尼替尼(Sunitinib)；及治療胃腺癌的曲妥珠單抗(Trastuzumab)）*
極度昂貴藥物計劃	新增藥物	- 兩種藥物 *（治療因原發性缺乏N-乙醯谷氨酸合酶、甲基丙二酸血症或丙酸血症而引起長期高氨血症的卡谷氨酸(Carglumic acid)；及治療陣發性夜間血紅素尿症的伊普可泮(Iptacopan)）*	沒有

[5] 貝伐珠單抗(Bevacizumab)仍在首階段計劃的涵蓋範圍內至 2025 年 5 月底，用於其他適應症以治療肝細胞癌（聯合阿替利組單抗(Atezolizumab)）。其後，兩種適應症改納入撒瑪利亞基金涵蓋範圍。

[6] 奧希替尼(Osimertinib)仍在首階段計劃的涵蓋範圍內用於治療肺癌的另一種適應症，作為單一藥物療法，用於具有表皮生長因子受體(EGFR)外顯子 19 缺失或外顯子 21(L858R)替代突變的 IB 至 IIIA 期非小細胞肺癌成年患者，在完全切除腫瘤手術後的輔助治療。

[7] 匹博利組單抗(Pembrolizumab)仍在首階段計劃的涵蓋範圍內用於其他適應症以治療肺癌 — (i)聯合培美曲塞及含鉑化療，用於沒有表皮生長因子受體(EGFR)或間變性淋巴瘤激酶(ALK)基因突變的轉移性非鱗狀非小細胞肺癌的患者，而其 PD-L1 水平腫瘤比例評分為 1-49%，作一線治療；及(ii)聯合培美曲塞及鉑類化療，用於沒有表皮生長因子受體(EGFR)或間變性淋巴瘤激酶(ALK)基因突變的轉移性非鱗狀非小細胞肺癌的患者，且未知或沒有 PD-L1 表達的一線治療；及用於另一種適應症以治療淋巴癌 — 單一治療用於三歲或以上的兒童患者，治療復發或難治性典型何傑金氏淋巴瘤，而患者曾接受自體幹細胞移植治療但無效，或無法接受自體幹細胞移植治療且曾接受至少兩種其他治療；及用於其他適應症以治療頭頸癌及腎細胞癌。

[8] 尼伏人單抗(Nivolumab)仍在首階段計劃的涵蓋範圍內，用於另一種適應症以治療胃腺癌、胃食道交界處腺癌或食道腺癌。

[9] 尼伏人單抗(Nivolumab)與伊匹木單抗(Ipilimumab)仍在首階段計劃的涵蓋範圍內，用於另一種適應症以治療肺癌。

[10] 阿替利組單抗(Atezolizumab)仍在首階段計劃的涵蓋範圍內，用於其他適應症以治療肺癌。

[11] 來那度胺(Lenalidomide)仍在首階段計劃的涵蓋範圍內，聯合達雷木單抗(Daratumumab)用於另一種適應症以治療多發性骨髓瘤。

計劃		2024/25年度之變更[3]	2025/26年度之變更[4] *（截至2025年5月底）*
	新增或放寬適應症	- 一種適應症 *（替沙侖賽(Tisagenlecleucel)）*	沒有
	藥物改納入撒瑪利亞基金涵蓋範圍	沒有	- 一種藥物／適應症 *（氯苯唑酸(Tafamidis)）*
醫療裝置計劃	**新增項目**	沒有	- 一種醫療裝置 *（血管外心臟植入式除顫器(Extravascular Implantable Cardioverter Defibrillator)）*
	擴闊／修訂適應症範圍	沒有	- 一種適應症 *（經皮導管肺動脈瓣植入術(Percutaneous Pulmonary Valve Implantation)）*

6. 上述新增藥物／適應症／非藥物項目的詳情載於**附件5**，而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則載於**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2025年3月31日，首階段計劃及極度昂貴藥物計劃分別涵蓋29種自費癌症藥物[12]及12種極度昂貴藥物[13]，而醫療裝置計劃涵蓋六種在體內設置的醫療裝置。至於首階段計劃曾涵蓋的維莫非尼(Vemurafenib)則由於已出現其他新的治療選擇，根據醫管局數據顯示近年並無病人使用該藥物，故已由2025年4月起從醫管局藥物名冊及首階段計劃涵蓋範圍中剔除。隨着所有新增藥物／適應症、新醫療裝置及擴闊現有醫療裝置的適應症範圍，以及將首階段計劃及極度昂貴藥物計劃的多種藥物改納入撒瑪利亞基金涵蓋範圍的安排於2025年5月底正式實施（已於2025年4月向醫務發展委員會匯報），首階段計劃、極度昂貴藥物計劃及醫療裝置計劃分別涵蓋**23種自費藥物[14]、11種極度昂貴藥物[15]及七種在體內設置的醫療裝置[16]**。

8. 為了能夠讓病人及早使用合適的新藥，藥事管理委員會自2018年起增加將新藥納入撒瑪利亞基金和關愛基金醫療援助項目涵蓋範圍建議的檢討次數，由每年一次增至兩次。除了政府新藥審批的新機制（即「1+」機制）外，醫管局亦已優化入藥制度及訂立納入安全網藥物優次順序的編配工作。由2025年第一季起，藥物建議委員會獲優化職能，負責向藥事管理委員會建議納入安全網藥物的優次順序，並由藥事管理委員會負責審批藥物建議委員會的相關建議。藥物建議委員會亦於其季度會議中加強處理符合納入安全網藥物的優次順序，由每年兩次增至四次。在新工作流程[17]下，

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[12] 包括於 2024/25 年度為首階段計劃引入兩種新藥物，以及將五種藥物改納入撒瑪利亞基金涵蓋範圍。

[13] 包括於 2024/25 年度為極度昂貴藥物計劃引入兩種新藥物。

[14] 於 2025 年 4 月，將一種藥物從醫管局藥物名冊及首階段計劃中剔除。另外於 2025 年 5 月，為首階段計劃引入兩種新藥物，以及將七種藥物改納入撒瑪利亞基金涵蓋範圍。

[15] 於 2025 年 5 月，將極度昂貴藥物計劃的一種藥物改納入撒瑪利亞基金涵蓋範圍。

[16] 於 2025 年 5 月，為醫療裝置計劃引入一種新醫療裝置。

[17] 新工作流程已於 2024 年 9 月 23 日討論的內務會議文件第 1981 號「優化醫院管理局藥物管理以加快引入新藥的程序，並提倡安全、具成本效益及合理用藥」向醫管局大會匯報。

將新藥納入醫管局藥物名冊及安全網資助範圍的整個過程由18個月大幅縮短至九個月。新藥評估及引入程序的新舊流程載於**附件8**。

獲批申請宗數及資助金額

9. 於2024/25財政年度（2024年4月1日至2025年3月31日），三個基金醫療援助項目的獲批申請宗數、獲批資助總額及每宗申請平均獲批資助金額概列如下：

計劃	獲批申請宗數	獲批資助總額（百萬元）	每宗申請平均獲批資助金額（元）
首階段計劃	1 991	581.85	292,241
極度昂貴藥物計劃	103	219.94	2,135,323
醫療裝置計劃	239	62.63	262,030

首階段計劃涉及資助額最多之藥物

10. 首階段計劃2024/25年度涉及資助額最多之藥物是用於治療肺癌的匹博利組單抗(Pembrolizumab)及奧希替尼(Osimertinib)；以及用於治療肝癌的阿替利組單抗(Atezolizumab)及貝伐珠單抗(Bevacizumab)。於2024/25年度，就這些藥物／適應症獲批的資助總額共2億676萬元，佔藥物申請獲批的資助總額36%；每宗申請平均獲批資助金額約340,000元。

財政狀況

三個醫療援助項目 2024/25 年度經審計的財務報表

11. 三個基金醫療援助項目截至2025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2057號「關愛基金醫療援助項目2024/25年度經審計財務報表」，以供成員審批。

三個醫療援助項目 2025/26 年度指標性預算

12. 根據上文第4段所述的簡化審批程序，三個項目2025/26年度的指標性資助批核預算及行政開支預算分別於2024年11月及2025年1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[18]	1,223.00	473.00	158.00	1,854.00
行政開支預算[19] *（各項計劃的行政開支預算分目載於**附件9**）*	30.57	11.82	3.95	46.34

質素保證

臨床審核

13. 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。如同於2024年6月向醫管局大會的匯報[1]，醫管局因應相關申請宗數及批出資助金額而選取了於2022/23年度獲批的下列項目申請進行臨床審核：(a)以奧希替尼作為用於具有表皮生長因子受體(EGFR)基因突變呈陽性的非小細胞肺癌並伴有中樞神經系統轉移的成年患者之第一線治療；及(b)經導管三尖瓣修復術。多名相關專科醫生組成臨床審核團隊，為抽選的21宗用以治療非小細胞肺癌的奧希替尼個案及四宗經導管三尖瓣修復術個案[20]進行同儕審核，以檢視基金申請的轉介過程是否符合當時的臨床指引。

14. 根據臨床審核的結果，在被抽選的21宗奧希替尼個案中，有19宗(90%)符合當時的臨床指引，而其餘兩宗則以追溯方式獲特殊考慮後被列作符合指引的個案[21]；至於另外四宗經導管三尖瓣修復術的抽選個案亦全部符合當時的臨床指引。有關審核報告已發予相關統籌委員會及中央委員會。在跟進兩宗曾以追溯方式獲特殊考慮個案的工作方面，團隊已向相關轉介部門及醫院管理層發出信件以作提醒，強調往後須於開展療程前就基金援助提出特殊考慮的申請並在開展治療前取得基金批核的重要性。

15. 因應過往一年的已批核個案數目及批出資助金額，醫管局選取了適用於治療未曾接受全身療法的晚期或無法切除肝細胞癌的成年患者之阿替利組單抗及貝

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[18] 資助批核預算包括 15%備用金以作緩衝用途。

[19] 包括人手開支及其他行政開支，佔指標性資助批核預算的 2.5%，並低於既定機制下 5%的上限。

[20] 符合抽選藥物或非藥物獲批個案 5%的目標。

[21] 根據基金的臨床指引，其中一項資格準則為*「經病理學證實患有具活化表皮生長因子受體(EGFR)基因突變的轉移性非小細胞肺癌的成年患者（18 歲或以上）」*。臨床審核員認為，兩宗奧希替尼(Osimertinib)個案在申請基金資助時並未經病理學證實為非小細胞肺癌，因此不符合相關資格準則。轉介部門澄清指，該兩宗個案因其臨床狀況及手術風險而未能進行活組織切片檢查，但已進行血漿表皮生長因子受體測試。臨床審核團隊在檢視審核結果時雖對血漿表皮生長因子受體測試能否視作病理學證實的診斷存在不同意見，但一致認為該兩宗個案屬臨床可接受情況，並建議將其列作「以追溯方式獲特殊考慮的符合指引個案」。臨床腫瘤科統籌委員會其後亦檢視相關臨床指引，並建議對使用奧希替尼的臨床指引維持不變，在為未經病理學證實的個案向基金申請資助時，應作出特殊申請。

伐珠單抗，以及全皮下心臟植入式除顫器的個案進行另一輪臨床審核。在2023/24及2024/25年度（截至2024年9月30日）獲批的個案中，審核了16宗阿替利組單抗及貝伐珠單抗個案及八宗全皮下心臟植入式除顫器個案[20]。有關臨床審核正在進行中，而審核結果將會向醫管局關愛基金行政委員會匯報。

16. 為了能夠及時進行臨床審核及增加整體樣本數量以提高審核樣本的代表性，關愛基金辦事處已就於2025/26年度實施以下針對藥物申請臨床審核的優化措施與相關持份者溝通，包括提醒他們根據現行臨床指引轉介有需要的病人申請安全網的援助：

(a) 由醫生進行的臨床審核抽樣工作由按年進行改為按季進行，而樣本數量須至少為已獲批個案的5%，以便及時評估上一季度獲批申請是否完全符合相關藥物／適應症現行的臨床指引；及

(b) 引入由臨床藥劑師進行的每月審核，於每個聯網每月抽選五宗個案（即每年420宗個案），集中審核「臨床資格」及「排除條件」是否符合指引。

經濟審查審核

17. 為確保醫務社會服務部就基金申請個案的經濟審查遵從既定指引，並適時提出改善建議，醫管局會進行經濟審查審核。

18. 就2024年1月1日至2024年12月31日期間的申請個案，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，抽選了共72宗基金申請個案[22]，對相關經濟審查文件進行同儕審核。所有經審核之抽選個案均完全符合就當時指引列載主要項目之所需資料提供適當證明文件的要求，例如病人身份證明文件及已簽署的病人聲明書。審核過程中亦發現五宗個案的收入及保險價值計算出錯，導致病人分擔額受到影響，相關退款及欠款已按現行程序完成處理。有關的醫院管理層會獲告知審核結果。

19. 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。審核報告亦會發給所有醫院醫務社會服務部及社會福利署總辦事處傳閱。有關的醫院醫務社會服務部已採取改善措施，包括與員工溝通，以及加強內部覆核與監察機制。

已批核個案之覆核

20. 為確保公帑用得其所，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2023/24及2024/25年度獲批之申請，截至2025年4月30日，共抽選了3 041宗個案[23]由聯網覆核組進行覆核。有關基金醫療援助項目已

[22] 符合抽選已獲批非綜合社會保障援助（**綜援**）個案（包括(a)非藥物申請所有獲批資助金額，及(b)藥物申請獲批資助金額為 30 萬元或以上）5%的目標。

[23] 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、10 萬元至 30 萬元以下，以及 10 萬元以下。

批核個案的覆核結果，將於2025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

21. 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的基金網頁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，並安排不同對內及對外的宣傳措施。對內方面，醫管局會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。

22. 醫管局流動應用程式HA Go中的「醫療費用援助一站通」（**一站通**）已於2022年分階段推出，目前已支援多項功能，包括提供計算程式讓病人事先自行評估其財務狀況是否符合申請資格；以推送通知加強與病人就財務評估及批核後覆核申請的溝通；申請狀況及資助使用情況查閱功能以提高透明度；方便病人提交所需證明的文件上傳功能；以及讓病人在網上填寫撒瑪利亞基金／關愛基金醫療援助項目的自助申請功能。

23. 於2024年11月至2025年4月期間，平均每月超過7 500名HA Go正式會員使用一站通程式，較2024年同期增加283%；另外每月有超過930名獲撒瑪利亞基金／關愛基金援助的病人使用該程式，較去年同期增加35%。

醫院管理局
HAB\PAPER\365
2025 年 6 月 19 日

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

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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 sixth term CoP has commenced on 1 July 2024. Two Task Forces have been set up under the sixth 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.

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.

(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.

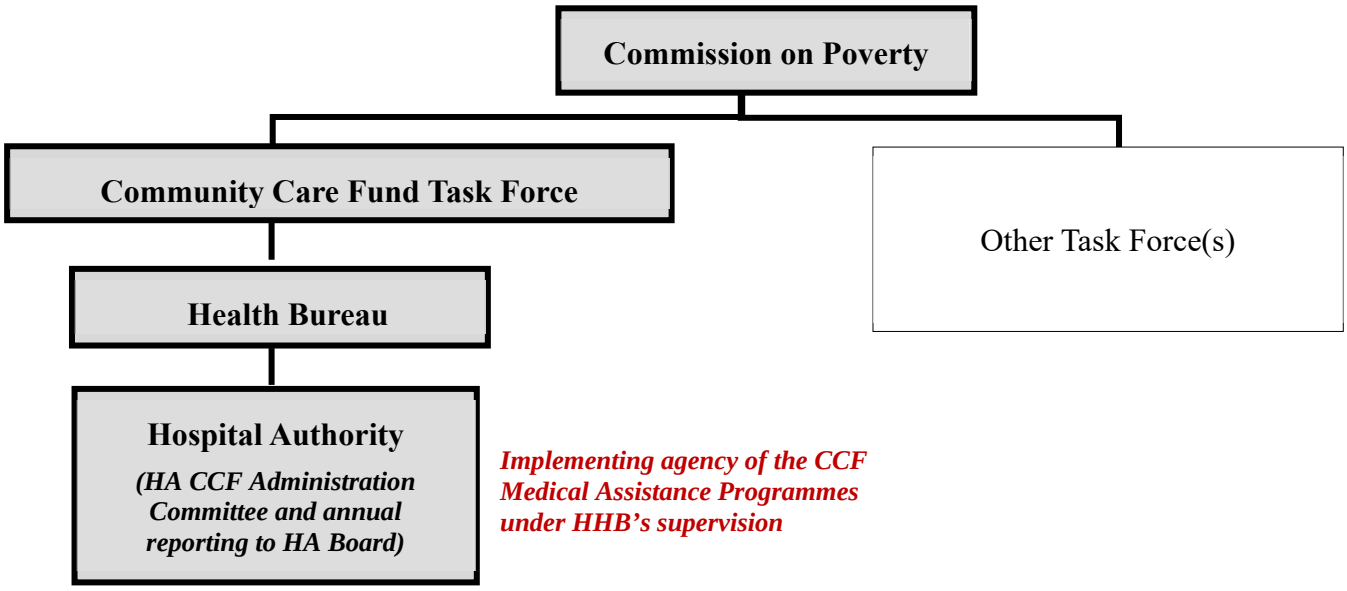
(c) **Subsidy for Eligible Patients of HA to Purchase Specified Implantable Medical Devices for Interventional Procedures (MD Programme)** was introduced on 1 August 2017. It provides financial assistance to needy HA patients to have early access to specified implantable medical devices for interventional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

↓

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

↓

Recommendation on prioritisation made by **Drug Management Committee (DMC)[4]** for drugs**,** and **Medical Device Advisory Committee** for medical devices

↓

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

↓

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.

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

[4] With effect from May 2025, Drug Advisory Committee (DAC) has taken up the function of recommending DMC the self-financed drugs prioritised for safety net coverage, and DMC will endorse DAC's recommendations on drug prioritisation for safety net coverage. With the enhancement of prioritisation of self-financed drugs for safety net coverage by DAC through its quarterly meeting, the safety net prioritisation will increase from two to four times per year.

Drugs Covered by the First Phase Programme
(As at end May 2025)

Self-financed drugs:
(Items shown in **bold** *are newly introduced in 2024/25 while those shown in italics are newly introduced in 2025/26)*

No.	Drug	Designated type of cancer	Designated clinical indications
1	*Abemaciclib*	*Breast cancer*	*With endocrine therapy as adjuvant treatment of hormone receptor positive (HR+ve), human epidermal growth factor receptor 2 negative (HER2-ve) early breast cancer in adults with at least four positive axillary lymph nodes*
2	Acalabrutinib	Lymphoma	For adult patients with relapsed or refractory mantle cell lymphoma
3a	Atezolizumab	Lung cancer	As monotherapy for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression >=50% tumour cells (TC) and who do not have epidermal growth factor receptor (EGFR) mutant or anaplastic lymphoma kinase (ALK)-positive NSCLC
3b			**In combination with carboplatin and etoposide for first-line treatment of adult patients with extensive-stage small cell lung cancer**
4	Avelumab	Bladder cancer	Monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy
5a	Daratumumab and Bortezomib	Multiple myeloma	In combination with thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant
6			
5b	**Daratumumab and Lenalidomide**	**Multiple myeloma**	**In combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy**
7			
8a	Ibrutinib	Lymphoma	As a single agent or in combination with rituximab for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) with MYD88 gene mutation who have received at least one prior therapy
8b		Leukaemia	**As monotherapy for the treatment of adult patients with previously untreated Chronic Lymphocytic Leukaemia (CLL) without del17p or TP53 gene AND (1) Cumulative Illness Rating Scale (CIRS>6; or (2) Creatinine Clearance (CrCl) <70 mL/min; or (3) unsuitable for full dose fludarabine or bendamustine based therapies**

No.	Drug	Designated type of cancer	Designated clinical indications
9 10	Isatuximab and Pomalidomide	Multiple myeloma	In combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy
11a	Lenvatinib	Thyroid cancer	Treatment of adult patients with progressive, locally advanced or metastatic, differentiated thyroid carcinoma (papillary/follicular/poorly differentiated/oncocytic carcinoma), refractory to radioactive iodine
11b 17a	**Lenvatinib and Pembrolizumab**	**Uterine cancer**	**Treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by a validated test, or not microsatellite instability-high (MSI-H), who have disease progression following prior platinum-based chemotherapy in any setting and are not candidates for curative surgery or radiation**
12	Neratinib	Breast cancer	For extended adjuvant treatment of adult patients with early-stage HR+ve, human epidermal growth factor receptor 2 positive (HER2+ve), breast cancer (>1cm or lymph node-positive) and who completed adjuvant trastuzumab-based therapy less than one year ago
13	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
14a	Nivolumab	Gastric, gastroesophageal junction or esophageal adenocarcinoma	In combination with fluoropyrimidine- and platinum-based combination chemotherapy for the 1st line treatment of adult patients with HER2-ve advanced or metastatic gastric, gastroesophageal junction or esophageal adenocarcinoma whose tumours express PD-L1 with CPS>=5
14b 15	Nivolumab and Ipilimumab	Lung cancer	In combination with 2 cycles of platinum double chemotherapy for first-line treatment of adult patients with metastatic or recurrent squamous NSCLC with no EGFR or ALK genomic tumour aberrations
16	**Osimertinib**	**Lung cancer**	**As monotherapy for the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA NSCLC whose tumours have EGFR exon 19 deletions or exon 21(L858) substitution mutations**
17b	Pembrolizumab	Lung cancer	In combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic nonsquamous NSCLC with PD-L1 expression (Tumour Proportion Score 1-49%) with no EGFR or ALK genomic tumour aberrations
17c			**In combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic non-squamous NSCLC with unknown or no PD-L1 expression with no EGFR or ALK genomic tumour aberrations**

No.	Drug	Designated type of cancer	Designated clinical indications
17d	Pembrolizumab	Lymphoma	As monotherapy for the treatment of paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option
17e		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 tumours express PD-L1 (CPS >=1) as determined by a validated test
17f		*Renal cell carcinoma*	*For the adjuvant treatment of patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions*
18a 19a	**Polatuzumab Vedotin and Rituximab**	**Lymphoma**	**In combination with cyclophosphamide, doxorubicin, and prednisone/prednisolone for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) and have International Prognostic Index (IPI) score 3-5**
18b 19b 20	Polatuzumab Vedotin and Rituximab and Bendamustine	Lymphoma	For the treatment of adult patients with relapsed/refractory DLBCL who are not candidates for haematopoietic stem cell transplant
21	*Selinexor*	*Multiple myeloma*	*In combination with dexamethasone for multiple myeloma in adult patients who have received >= 4 prior therapies and refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and with disease progression on last therapy*
22	**Selumetinib**	**Neurofibromatosis**	**For the treatment of symptomatic, inoperable plexiform neurofibromas (PN) actively progressing on imaging in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 to 18 years**
23	**Zanubrutinib**	**Lymphoma**	**Monotherapy for the treatment of adult patients with WM who have received at least one prior therapy**

Drugs Covered by the Ultra-expensive Drugs Programme
(As at end May 2025)

Ultra-expensive Drugs
(Items shown in **bold** *are newly introduced in 2024/25)*

No.	Drug	Designated clinical indications
1	Burosumab	X-linked hypophosphataemia
2	**Carglumic acid**	**For treatment of chronic hyperammonaemia in N-acetylglutamate synthase (NAGS) deficiency, methylmalonic acidemia (MMA) or propionic acidemia (PA)**
3	Dinutuximab Beta	Treatment of high-risk or relapse/refractory neuroblastoma
4	Eculizumab	Atypical haemolytic uraemic syndrome (aHUS)
5	**Iptacopan**	**Paroxysmal nocturnal haemoglobinuria (PNH)**
6	Nusinersen	Infantile Onset Spinal Muscular Atrophy (SMA) / Childhood Onset SMA / Pre-symptomatic SMA
7	Onasemnogene abeparvovec	Infantile Onset SMA / Pre-symptomatic SMA
8	Ravulizumab	PNH / aHUS
9	Risdiplam	Infantile Onset SMA / Childhood Onset SMA
10	Tafamidis Meglumine	For the treatment of transthyretin amyloidosis in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment
11	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
		For the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

Medical Devices Covered by the Medical Devices Programme
(As at end May 2025)

Implantable Medical Devices
(Item shown in italics is newly introduced in 2025/26)

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
7	*Extravascular Implantable Cardioverter Defibrillator (EV-ICD)*

[1] With the expansion of indication, the 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)".

Details of new drugs/indications/non-drug items introduced in 2024/25 and 2025/26 (Up to end May 2025)

2024/25

(i) New drugs/indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Selumetinib	New drug/indication	For the treatment of symptomatic, inoperable plexiform neurofibromas (PN) actively progressing on imaging in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 to 18 years	25 May 2024
2.	Zanubrutinib	New drug/indication	Monotherapy for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy	25 May 2024

- UED Programme

No.	Drugs	Change	Indications	Effective Date
1.	Carglumic acid	New drug/indication	For the treatment of chronic hyperammonaemia in N-acetylglutamate synthase (NAGS) deficiency, methylmalonic acidemia (MMA) or propionic acidemia (PA)	11 Jan 2025
2	Iptacopan	New drug to existing indication	Paroxysmal Nocturnal Haemoglobinuria (PNH)	11 Jan 2025

(ii) New or relaxed indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Daratumumab and Lenalidomide	New indication to existing drugs	In combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy	25 May 2024
2.	Lenvatinib and Pembrolizumab	New indication to existing drugs	Treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by a validated test, or not microsatellite instability-high (MSI-H), who have disease progression following prior platinum-based chemotherapy in any setting and are not candidates for curative surgery or radiation	25 May 2024
3.	Osimertinib	New indication to existing drug	As monotherapy for the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21(L858) substitution mutations	25 May 2024
4.	Polatuzumab Vedotin and Rituximab	New indication to existing drugs	In combination with cyclophosphamide, doxorubicin, and prednisone/prednisolone for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) and have International Prognostic Index (IPI) score 3-5	25 May 2024
5	Atezolizumab	New indication to existing drug	In combination with carboplatin and etoposide for first-line treatment of adult patients with extensive stage small cell lung cancer	14 Dec 2024
6	Ibrutinib	New indication to existing drug	As monotherapy for the treatment of adult patients with previously untreated Chronic Lymphocytic Leukaemia (CLL) without del17p or TP53 gene AND (1) Cumulative Illness Rating Scale (CIRS) >6; or (2) Creatinine Clearance (CrCl) <70 mL/min; or (3) unsuitable for full dose fludarabine or bendamustine based therapies	14 Dec 2024
7	Pembrolizumab	New indication to existing drug	In combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic non-squamous NSCLC with unknown or no PD-L1 expression with no EGFR or anaplastic lymphoma kinase (ALK) genomic tumour aberrations	14 Dec 2024

- UED Programme

No.	Drug	Change	Indication	Effective Date
1.	Tisagenlecleucel	New indication to existing drug	For the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy	25 May 2024

2025/26 (Up to end May 2025)

(i) New drugs/indications

- First Phase Programme

No.	Drugs	Change	Indications	Effective Date
1.	Abemaciclib	New drug/indication	With endocrine therapy as adjuvant treatment of hormone receptor positive (HR+ve), human epidermal growth factor receptor 2 negative (HER2-ve) early breast cancer in adults with at least four positive axillary lymph nodes	30 May 2025
2.	Selinexor	New drug/indication	In combination with dexamethasone for multiple myeloma in adult patients who have received >= 4 prior therapies and refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and with disease progression on last therapy	30 May 2025

(ii) New or relaxed indication

- First Phase Programme

No.	Drug	Change	Indication	Effective Date
1.	Pembrolizumab	New indication to existing drug	For the adjuvant treatment of patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions	30 May 2025

(iii) New non-drug item / Expansion of indication for non-drug item

- Medical Devices Programme

No.	Non-Drug items	Change	Indications	Effective Date
1.	Extravascular Implantable Cardioverter Defibrillator (EV-ICD)	New medical device	Patients with Class I and Class II indication and with restrictions of limited venous access and/or prior infection (i) as an alternative to Subcutaneous Implantable Cardioverter Defibrillator (S-ICD); or (ii) for whom required antitachycardia pacing for prevention of sudden cardiac death	30 May 2025
2.	Percutaneous Pulmonary Valve implantation (PPVI)	Expansion of indication for existing medical device	For dysfunctional native right ventricular outflow tract	30 May 2025

Chronology of Re-positioning of Items
from Community Care Fund (CCF) Medical Assistance Programme
(First Phase Programme)
to Samaritan Fund & Special Drugs of Hospital Authority (HA) Drug Formulary
(As at end May 2025)

- *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 (RCC)	May 2022
14.	Abiraterone for Prostate Cancer	Dec 2022
15. & 16.	Enzalutamide for Prostate Cancer – 1st line and 2nd line	Dec 2022
17.	Obinutuzumab for CLL	Dec 2022
18.	Axitinib for RCC	Dec 2022
19.	Ceritinib for NSCLC	Dec 2022
20.	Nivolumab # for Skin Cancer	May 2023
21.	Dabrafenib and Trametinib for Skin Cancer	May 2023
22.	Palbociclib for Breast Cancer	May 2023
23.	Ribociclib for Breast Cancer	May 2023
24.	Everolimus for Breast Cancer	May 2023
25.	Trastuzumab emtansine (T-DM1) for Breast Cancer	May 2023
26. 27. & 28.	Brentuximab Vedotin for Lymphoma – for three indications	May 2023
29.	Abemaciclib # for Breast Cancer	Dec 2023

No.	Drug and Type of Cancer	Effective Date
30.	Inotuzumab Ozogamicin for Leukaemia	Dec 2023
31.	Lenvatinib # for Liver Cancer	Dec 2023
32.	Atezolizumab # for NSCLC	Dec 2023
33.	Brigatinib for NSCLC	Dec 2023
34.	Durvalumab for NSCLC	Dec 2023
35.	Pembrolizumab # for NSCLC	Dec 2023
36.	Nivolumab # for NSCLC	Dec 2023
37.	Nivolumab # for Skin Cancer	Dec 2023
38.	Abiraterone for Prostate Cancer	May 2024
39.	Olaparib for Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer	May 2024
40.	Osimertinib # for NSCLC	May 2024
41.	Pembrolizumab # for Bladder Cancer	May 2024
42.	Bevacizumab for Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer	Dec 2024
43.	Dabrafenib and Trametinib for Skin Cancer	Dec 2024
44.	Gemtuzumab Ozogamicin for Leukaemia	Dec 2024
45.	Nivolumab # for Head and Neck Cancer	Dec 2024
46.	Nivolumab # and Ipilimumab # for RCC	Dec 2024
47.	Atezolizumab # and Bevacizumab for Liver Cancer	May 2025
48.	Bevacizumab for CRC	May 2025
49.	Ixazomib and Lenalidomide # for Multiple Myeloma (MM)	May 2025
50.	Lapatinib for Breast cancer	May 2025
51.	Lorlatinib for NSCLC	May 2025
52.	Pegylated Liposomal Doxorubicin for Ovarian Cancer	May 2025
53.	Pembrolizumab # for NSCLC	May 2025
54.	Pembrolizumab # for Lymphoma	May 2025
55.	Sunitinib for RCC	May 2025
56.	Trastuzumab for Gastric Carcinoma	May 2025

Osimertinib, Nivolumab, Abemaciclib, Lenvatinib, Atezolizumab, Pembrolizumab, Ipilimumab and Lenalidomide are still under CCF for other indications

- *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 (As at end May 2025)

No.	Drug and Type of Disease	Effective Date
1.	Eculizumab for Paroxysmal Nocturnal Haemoglobinuria (PNH)	Jul 2020
2.	Tafamidis for the treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)	May 2025

Details of relaxation/revision of clinical guidelines in 2024/25 and 2025/26 (Up to end May 2025)

(i) 2024/25

- First Phase Programme

No.	Drugs	Indications	Revision	Effective Date
1.	Bevacizumab	First line treatment of RAS mutant metastatic colorectal cancer in combination with chemotherapy in adult patients indicated for intensive treatment / 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	Revision on one of the eligibility criteria: - Have not previously ~~received~~ *progressed on* any chemotherapy or targeted agents for his/her metastatic disease.	25 May 2024
2.	Sunitinib	First-line treatment for advanced renal cell carcinoma	Revision on eligibility criteria: - Sunitinib is recommended as a first-line treatment option for people with advanced and/or metastatic renal cell carcinoma with clear cell component who ~~are suitable for immunotherapy and~~ have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, *yet considered not suitable for currently available combination systemic therapy*. The requirement of assessing the treatment response after the patient has received first 4-week of treatment was removed from the "Monitoring and Reassessment" section.	25 May 2024

No.	Drugs	Indications	Revision	Effective Date
3.	Lorlatinib	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	Revision on one of the termination criteria: - Treatment should be terminated if the patient develops *systemic* progressive disease during treatment *while systemic progressive disease is defined as diseases beyond treatment by local therapy*.	25 May 2024
4.	Acalabrutinib	For adult patients with relapsed or refractory mantle cell lymphoma	Modifications of the clinical guidelines were made due to update of patient access programme (PAP) for Acalabrutinib: - Cap ceiling of PAP was updated from 840 capsules to *896* capsules.	11 Oct 2024
5.	Atezolizumab and Bevacizumab	For the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy	Addition of new pretreatment medical assessment: - *OGD assessment prior to treatment initiation within 6 months to ensure no untreated esophageal or gastric varices with bleeding or high risk of bleeding.*	14 Dec 2024
6.	Lapatinib	Human epidermal growth factor receptor 2 (HER2) positive advanced breast cancer with prior therapy including an Anthracycline, a Taxane and Trastuzumab	Revision on one of the exclusion criteria: - Patients who have ~~previously~~ failed *more than one line of* ~~another~~ HER2 targeted treatment in ~~addition to Trastuzumab (e.g. Lapatinib or T-DM1) for~~ palliative *setting* ~~treatment of breast cancer~~. Revision on one of the termination criteria to allow switching from Lapatinib to Trastuzumab emtansine (T-DM1) *or Trastuzumab deruxtecan* for once if intolerant to Lapatinib.	14 Dec 2024

No.	Drugs	Indications	Revision	Effective Date
7.	Lorlatinib	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	Removal of one of the exclusion criteria: - Patients who are taking strong CYP3A inducers Addition of two more points under pretreatment medical assessment: - *Discontinue concomitant use of strong CYP3A inducers before start Lorlatinib. A washout period of at least 3 half-lives of the inducer is recommended if possible after clinical assessment.* - *Avoid concomitant use of moderate CYP3A inducers or CYP3A inhibitors or consider dose adjustment of Lorlatinib if concomitant use is unavoidable.*	14 Dec 2024
8.	Niraparib	As monotherapy for the maintenance treatment of adult patients with advanced 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	Addition of one exclusion criterion: - *Patients received upfront and maintenance Bevacizumab*	14 Dec 2024
9.	Nivolumab and Ipilimumab	In combination with 2 cycles of platinum double chemotherapy for first-line treatment of adult patients with metastatic or recurrent squamous NSCLC with no EGFR or ALK genomic tumour aberrations	Removal of two exclusion criteria: - Patients with suspected autoimmune disease - Patients with positive test result for hepatitis B, hepatitis C virus or human immunodeficiency virus Revision on prescribing and dispensing section for better clarity of the PAP offer of Ipilimumab.	14 Dec 2024

- UED Programme

No.	Drug	Indication	Revision	Effective Date
1.	Nusinersen	Infantile Onset Spinal Muscular Atrophy (SMA) / Childhood Onset SMA / Pre-symptomatic SMA	Addition of exclusion criterion: - Prior treatment with onasemnogene abeparvovec Refinement of one of the exit criteria for pre-symptomatic SMA only, where patients with new onset of symptom(s) will exit the treatment criteria on the use of nusinersen for pre-symptomatic SMA and to be reviewed under the treatment criteria on the use of nusinersen*/ risdiplam* for symptomatic SMA.	11 Oct 2024
2.	Risdiplam	Infantile Onset SMA / Childhood Onset SMA	Addition of exclusion criterion: - Prior treatment with onasemnogene abeparvovec	11 Oct 2024
3.	Tisagenlecleucel	For adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	Revision on inclusion criteria: - Addition of ➢ "*at least one of which must be intensive regimen with curative intent*" as one of the required lines of systemic therapy for relapsed/refractory DLBCL; and ➢ *[Individual consideration for patients in cytopenic phase after chemotherapy]*; and ➢ footnote for DLBCL as "*DLBCL includes disease transformed from follicular lymphoma, high-grade B-cell lymphoma with MYC rearrangement plus rearrangement of BCL2, BCL6, or both genes (i.e., double- or triple-hit lymphoma). Primary mediastinal DLBCL is excluded*" - Removal of the inclusion criterion "*Has been previously treated with anthracycline-containing regimen for the lymphoma*" - Application submission to "*Central Assessment and Prioritisation Panel (CAPP)*".	14 Dec 2024

No.	Drug	Indication	Revision	Effective Date
			Refinement of exclusion criteria: - "*Prior treatment with any anti-CD19/anti-CD3 therapy or any other anti-CD19 therapy unless with CD19-positive expression*"; and - "*Active hepatitis B (defined as detectable HBV DNA in blood if serum HBsAg or AntiHBc positive) or hepatitis C (defined as detectable HCV RNA in blood if anti-HCV positive) infection - Except patients with HBV DNA less than 2000IU/ml and on antivirals*" Removal of the exclusion criterion "*Active central nervous system involvement by lymphoma*" and "*Epstein-Barr virus–positive DLBCL of the elderly*". Revision on prioritisation criteria for CAR-T therapy.	
4.	Tisagenlecleucel	For paediatric and young adult patients up to 25 years of age with relapsed or refractory B-Cell Acute Lymphoblastic Leukaemia (ALL)	Revision on inclusion criteria: - Addition of ➢ "*central nervous system (CNS) relapse*" as one of the clinical scenarios for relapsed/refractory B-Cell ALL; and ➢ "*[Individual consideration for patients in cytopenic phase after chemotherapy]*" - Refinement of the inclusion criterion "*detectable ALL and CD19 ALL positivity ~~in the bone marrow~~*" - Application submission to "*Central Assessment and Prioritisation Panel (CAPP)*" instead of "*Expert Panel*". Refinement of exclusion criteria: - "*An isolated extramedullary acute lymphoblastic leukaemia relapse (except CNS)*"; and	14 Dec 2024

No.	Drug	Indication	Revision	Effective Date
			- "*Active hepatitis B (defined as detectable HBV DNA in blood if serum HBsAg or AntiHBc positive) or hepatitis C (defined as detectable HCV RNA in blood if anti-HCV positive) infection - Except patients with HBV DNA less than 2000IU/ml and on antivirals*"; and - "*Prior treatment with any anti-CD19 therapy unless with CD19-positive expression*" Removal of the exclsuion criterion "*Known active CNS involvement by acute lymphoblastic leukaemia*" Revision on prioritisation criteria for CAR-T therapy.	
5.	Onasemnogene abeparvovec	Infantile Onset SMA / Pre-symptomatic SMA	Revision on one of the inclusion criteria: - *For treatment naïve:* preferably under the age of 6 months at the time of assessment. For those between the age of 7-12 months, ~~additional assessment will be carried out based on individual condition~~ *the application will be reviewed case-by case*" Revision on the use of therapy for newborn patients who initially tested positive for AAV9 but is anticipated to test negative for AAV9 after a period of few months, they can consider initiating treatment with nusinersen/risdiplam up to 90 days under CCF assistance. Following this, the commencement of Onasemnogene abeparvovec may be considered if fuflfilled the clinical criteria.	1 Mar 2025

(ii) 2025/26 (Up to end May 2025)

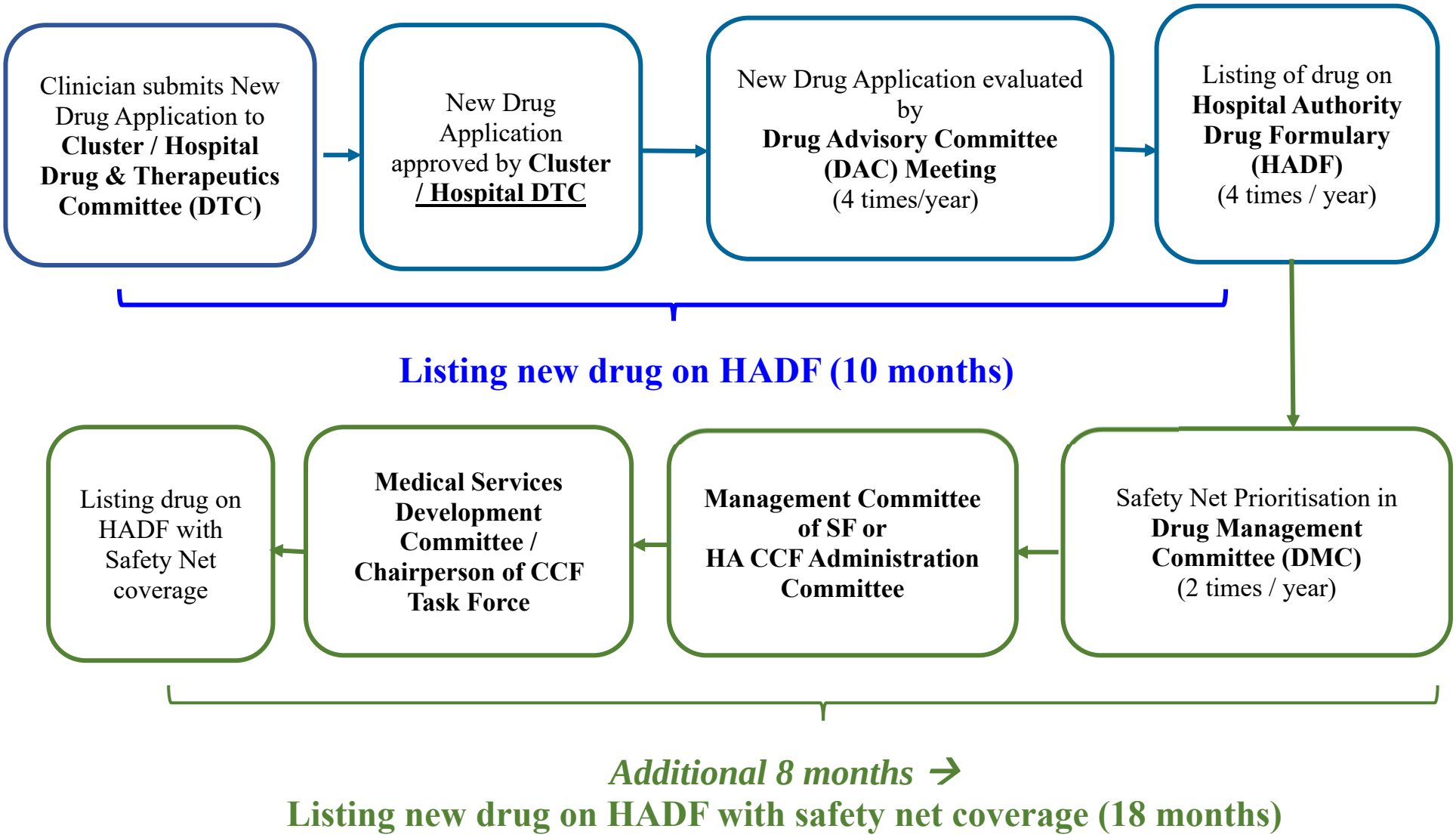
- First Phase Programme

No.	Drugs	Indications	Revision	Effective Date
1.	Daratumumab and Bortezomib	In combination with thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant	Modification made to restrict the consolidation phase of treatment to patients who meet the specific clinical requirements.	30 May 2025

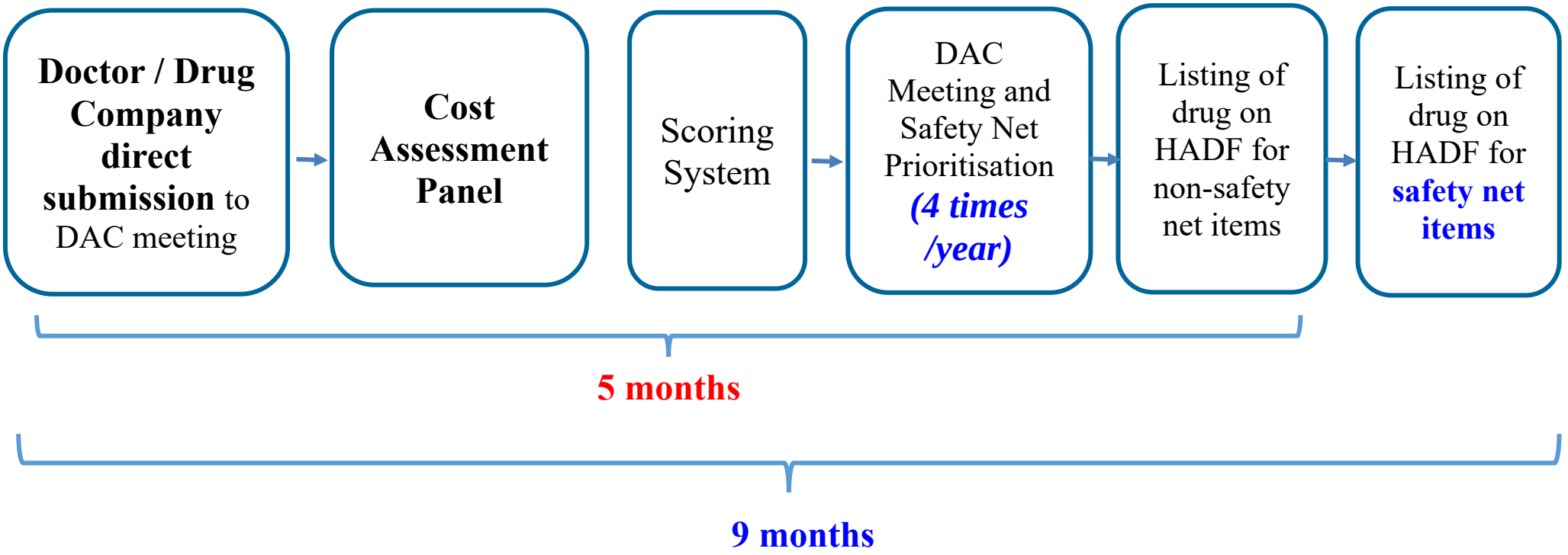
- UED Programme

No.	Drug	Indication	Revision	Effective Date
1.	Tisagenlecleucel	For the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy	Revision on prioritisation criteria.	26 Apr 2025

Past Workflow of New Drug Evaluation and Enlistment Process



New Workflow of New Drug Evaluation and Enlistment Process



The list of drugs/indications recommended for safety net inclusion will be put forward to relevant governance platforms for further deliberation and approval according to prevailing mechanism through meeting or circulation

Administrative cost budget for 2025/26 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	24.46	9.46	3.16	37.08
Computer system	2.00[1]	-	-	2.00
Audit fee[2]	-	-	-	-
Others	1.06	1.18	0.40	2.64
Contingency	3.05	1.18	0.39	4.62
Total	**30.57**	**11.82**	**3.95**	**46.34**

[1] The budget has included the estimated expenditure of computer system for the three Medical Assistance Programmes.
[2] With reference to the prevailing contract term, it is assumed that the external auditor would provide free audit services for the three Medical Assistance Programmes.