Global registration, reimbursement, and restrictions to direct-acting antiviral therapies for hepatitis C infection

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Abstract

Direct-acting antivirals for hepatitis C virus (HCV) infection have delivered high cure responses (>95%) and simplified HCV treatment management, permitting non-specialists to manage patients without advanced liver disease. We reviewed the registration, reimbursement (government subsidised), and restrictions of HCV therapies globally. Primary data collection occurred between November 2021 and July 2023 through the assistance of a global network of 166 HCV experts. Of 209 countries, we retrieved data for 160 (77%) countries. By mid-2023, 145 (91%) countries registered at least one of the following direct-acting antivirals (DAAs): sofosbuvir-velpatasvir, sofosbuvir-velpatasvir-voxilaprevir, glecaprevir-pibrentasvir, sofosbuvir-daclatasvir (either as combination therapy or separate), and sofosbuvir. 109 (68%) countries reimbursed at least one DAA combination therapy. Among low-and middle-income countries, LMICs (n=102), 89 (87%) registered at least one HCV DAA combination therapy and 53 (52%) reimbursed at least one DAA combination therapy. Among all countries with DAA therapy reimbursement (n=109), 66 (61%) countries required specialist prescribing, eight (7%) had retreatment restrictions, seven (6%) had an illicit drug use restriction, five (5%) had an alcohol use restriction, and three (3%) had liver disease restrictions. Global access to DAA reimbursement remains uneven with LMICs having comparatively limited reimbursement. To meet the World Health Organization (WHO) goals for HCV elimination, efforts should be placed on assisting countries, particularly LMICs, in increasing access to DAA reimbursement and removing reimbursement restrictions, especially prescriber type restrictions, to assure universal access.

Key words: hepatitis C virus, hepatitis C treatment, direct-acting antivirals, registration, reimbursement, restrictions

Introduction

An estimated 57 million people are living with chronic hepatitis C virus (HCV) worldwide.[1] HCV infection is associated with severe liver-related morbidity and mortality, resulting in a substantial global health burden.[2,3] In high income countries, HCV transmission primarily occurs through contaminated injecting equipment whereas in low- and middle-income countries (LMICs), most HCV transmission occurs in healthcare settings (e.g., lack of sterilised medical equipment), although transmission via injection drug use is on the rise in some LMICs.[4-7] The World Health Organization (WHO) has set targets to eliminate viral hepatitis as a global public health threat by 2030, including: ≥90% of people with HCV diagnosed and ≥80% of people diagnosed with HCV are treated.[8] The WHO absolute targets strive to reduce annual HCV incidence to ≤5/100,000 (≤2/100 in people who inject drugs, PWID) and annual mortality ≤2/100,000.[9] Few countries are currently on track to meet WHO targets,[10] underscoring an urgency for governments to more adequately respond.

All-oral direct-acting antiviral drugs (DAAs) with >95% cure responses have revolutionised HCV management, leading to declines in liver-related morbidity and mortality.[11-13] Due to the high list price of DAA therapies, many countries initially prioritised HCV treatment for persons with severe liver disease. In 2018, research on reimbursement restrictions to DAA therapies in the European Union and European Economic Area (EU/EAA) countries (n=35) found that nearly half (46%) had fibrosis stage restrictions (F2 or higher; METAVIR or equivalent).[14] Most European countries/jurisdictions (83%) also had prescriber restrictions limiting DAA prescribing to infectious disease specialists, hepatologists, and/or gastroenterologists.[14] In 2015, a USA study (n=50 plus the District of Columbia) found that the majority of states limited DAA reimbursement to advanced fibrosis (74%; F3 or higher), specialist prescribing (69%), and had drug and alcohol use restrictions (88%), although many

states have since eased these restrictions when DAAs costs were reduced.[15,16] Similarly, 2016 research on reimbursement restrictions to DAA access in Canada found that the majority of provinces/territories had fibrosis stage restrictions (up to 92% depending on DAA) and nearly half had prescriber restrictions (up to 42% depending on DAA), many of which have since been removed.[17,18] To date, there has been limited research on access and reimbursement of DAA therapy globally, especially in LMICs. There is also minimal research on restrictions to HCV retreatment due to virological treatment failure or reinfection from engagement in high-risk behaviours. In a meta-analysis (36 studies), the overall HCV reinfection rate among PWID was an estimated 5.9/100 person-years and hence, timely uptake of HCV retreatment is important to reduce HCV incidence and prevalence.[19] Further, many HCV policy studies focus on single countries or regions, missing an opportunity for multi-country analyses and comparisons.

The aims of the study were to review global registration status of HCV DAAs; reimbursement of DAAs (government reimbursed, subsidised or fee-free policy); and whether there were restrictions – prescriber type, liver disease stage, drug and alcohol use, and retreatment – to reimbursed DAAs.

Methodology

We reviewed the registration, reimbursement, and restrictions for HCV DAAs globally. Methods for assessing reimbursement restrictions to DAAs in Canada, Europe, and the USA were similar to those previously utilised.[14,15,17] For this review, we focused on whether people living with HCV (nationals of the country) could access subsidised DAAs (originators or generics) via government reimbursement, subsidy or fee-free policy. Our data collection pertained to DAA access to persons ≥18 years, given the lack of focus on children and HCV treatment management globally.[20]

Some LMICs accessed DAAs through a third-party agreement with a major international donor [e.g., Global Fund to Fight AIDS, Tuberculosis and Malaria, U.S President's Emergency Plan for AIDS Relief (PEPFAR)] or non-governmental organisation [e.g., Médicins Sans Frontières (MSF)]. These funding circumstances were mostly limited to specific population groups (e.g., providing HCV treatment without patient costs to persons co-infected with HIV and HCV) rather than broad population access. Such circumstances are unstable in the long-term due to changing donor priorities (e.g. MSF no longer supplies DAAs to Cambodia).[21] In these cases, we did not categorise the country as utilising a formal DAA reimbursement structure. Given that major international donors are not heavily involved in HCV service funding,[4] we did not anticipate that funding from these donors would be common.

Between August 2021 and October 2021, an initial grey literature search was conducted using Google (Mountain View, United States) by study authors ADM, ARW, AK, NB, DJ, and VD. Primary outcome data were extracted from publicly available sources including drug regulatory websites, online drug formularies, and HCV-related documentation, e.g., national

HCV guidelines and national HCV strategies. Data were recorded in a pre-piloted and pre-standardised database.

Next, a Network of global experts (primarily HCV and HIV) was generated. Attempts were made to connect with in-country experts in the field of infectious diseases, gastroenterology, hepatology, and addiction medicine. First, existing HCV contacts from the study authors were utilised to facilitate access to global experts working in the field. Second, in-country experts who contributed to our prior work on HCV DAA reimbursement restrictions in Europe were contacted.[14] Third, in circumstances in which there were no prior collaboration, potential global HCV and HIV experts were sourced from peer-reviewed publications available through PubMed. Last, in-country contacts were facilitated through UN agencies, including regional offices of the WHO and Joint United Nations Programme on HIV/AIDS (UNAIDS). Our aim was to have at least one in-country expert per country. Next, an email invite was sent (by JG) to the Network to explain the purposes of the research. Most in-country experts were contacted in English, with a few contacted in French, Spanish, or Portuguese. If the in-country expert agreed to participate, the extracted in-country data and verified sources were provided to them. When an expert agreed to participate but did not respond to subsequent emails, they were re-prompted twice, and if there was no response, another potential collaborator was contacted.

In circumstances where no country data had been found, we requested the in-country expert to facilitate access to official documentation related to primary study outcomes. The in-country experts were requested to provide verifiable sources such as online drug formularies and reimbursement website links/documentation and other relevant documentation (e.g., Ministry of Health press releases, Essential Medicines List). If national clinical practice guidelines

were not available, in-country experts were asked to clarify which regional clinical practice guidelines their country utilised (e.g., Asian Pacific Association for the Study of the Liver, European Association for the Study of the Liver, WHO). When HCV written documentation was not available, we confirmed this with in-country experts. As with prior research,[14] if the information of interest was not located in written documentation (e.g., clinical practice guidelines) or online where this information would expect to be located, this information was categorised as 'none stated'. If no information could be found for a specific country (which was unlikely if we had access to an in-country expert), this information was categorised as 'no information'. In-country experts were asked to provide written documentation in their country's language(s), which was translated using Google Translate. From November 2021 to July 2023, data were extracted from the provided documentation by ADM, ARW, and AK. In-country experts were sent follow-up emails to provide clarification of interpretation and verify recorded data in the tables and supplementary tables.

From November 2021 to July 2023, we contacted ~820 potential collaborators and received participation from 166 contacts. Among these in-country experts or newly developed Network (n=166) (i.e., the Global HCV and HIV Treatment Restrictions Group, appendix p 1), we facilitated the collection and extraction of information from 160/209 countries (77%). As with a previous review,[14] we reported on England, Northern Ireland, Scotland, and Wales jurisdictions separately (n=4). Svalbard and Jan Mayen and Greenland were treated as separate jurisdictions from Norway and Denmark, respectively. Regarding population size, we received information from countries that covered approximately ~7.4 billion persons, representing ~95% of the global population. Nearly all in-country experts are based within the country of interest. In June and July 2023, we reached out to the Network (n=166) to validate their country data and provide any updates.

The primary outcomes of interest were the: registration status of DAAs (generics or originators); whether these DAAs were reimbursed; and restrictions to accessing reimbursed DAAs. Data are presented globally and, in figure 1 by region: Asia, Central Asia, South Asia, Eastern Europe, Western Europe, Middle East and North Africa, Sub-Saharan Africa, North America, Latin America, Caribbean, Pacific Island States and Territories, and Australasia. Data were also presented based on country income classification (e.g., low-and middle income).[22]

Registration data of the following DAAs were collected: sofosbuvir-velpatasvir, sofosbuvir-velpatasvir-voxilaprevir, sofosbuvir, daclatasvir, and glecaprevir-pibrentasvir. In the case of sofosbuvir-daclatasvir combinations, we reported on sofosbuvir-daclatasvir combination therapy or daclatasvir and sofosbuvir available separately. Data collection was restricted to these DAAs to mostly focus on pan-genotypic therapies, while also recognising that sofosbuvir and daclatasvir and sofosbuvir may be more commonly utilised in LMICs. It was possible to have a DAA that was registered but not marketed (e.g., sofosbuvir in Czech Republic). In these circumstances, the DAA was still categorised as registered.

Regarding reimbursement, we extracted whether countries provided DAAs with subsidies. We did not record restrictions to DAAs through the private health insurance system. Most persons who are impacted by HCV infection make up marginalised population groups who are economically disenfranchised (~50% of the world's population have a daily salary <$2 USD, if employed at all) and our research aim was to characterise the proportion of global residents who could access DAAs regardless of income.[23]

Regarding restrictions to reimbursed DAAs, we recorded restrictions pertaining to prescriber-type, liver disease staging, illicit drug and/or alcohol use, and retreatment. If patients needed to fully pay out of pocket for DAAs, restriction data were not applicable (and collected), as patients could pay for DAAs without limitations (e.g., liver disease stage restrictions). We added a 'not applicable' category to the figures (figures 2-6) to include these circumstances.

Prescriber type categories were restriction (i.e., specialist only – general practitioner prescription not permitted), no restriction, none stated, no information, and not applicable (DAAs not reimbursed). If the country permitted non-specialists to prescribe, this was categorised as no restriction. In these cases, non-specialists may have had to complete a minimal education and/or training course, for example, but could still prescribe DAAs. In some countries, the implementation of health services is mandated by states/provinces, e.g., Canada, the USA, rather than national. Based on prior reviews,[15,17] this often results in considerable intra-country differences regarding DAA access (e.g., specialist prescribing restrictions in some states but not others). For Canada and the USA, we categorised the restriction based on how most provinces/states implemented the restriction (e.g., if most states require specialist only prescribing, this is categorised as specialist only).

Liver disease staging categories were: restriction ($\geq$F1 or higher), no restriction, none stated, no information, and not applicable. We noted when a minimum fibrosis stage (METAVIR or equivalent) was required to receive access to reimbursed DAAs. We did not record whether certain equipment (e.g., transient elastography) was required for the liver disease assessment because this data is infrequently mentioned in documentation.

Drug and alcohol use categories were: restriction, no restriction, none stated, no information, and not applicable. We recorded whether there were any mandatory drug and alcohol use restrictions (e.g., drug or alcohol use abstinence requirements). If patients had to receive reimbursed HCV treatment from specific centres this was categorised as no restriction given that DAA access was still possible, albeit limited.

HCV DAA retreatment categories were: restriction, no restriction, none stated, no information, and not applicable. An example of a retreatment restriction is whether there was a maximum number of times a patient could receive reimbursed HCV treatment. We did not differentiate whether the reimbursement policy differed regarding the cause of reinfection (e.g., treatment failure or risk behaviours).

Study authors (ADM, ARW, AK, EBC, AW, JG) held regular meetings to review the interpretation of data and ultimate categorisation of data. When we could not verify the validity of the data retrieved from a specific country (e.g., did not hear back from the in-country expert following a prompt), we deferred to the most recent written document available as the final source. Discrepancies were decided by consensus. All data and tables were organised in Excel (version 2023). Maps were made with Tableau (version 2023.1). Authors AW and EBC assisted with the production of tables and figures.

Role of the funding source

The funding source did not have any input into the study design, data collection, data analysis, interpretation of the data, writing of the report, or the decision to submit the manuscript for publication. The corresponding author had full access to all the data in this study and final responsibility for the decision to submit the publication.

Findings

Of the 160 countries from which we retrieved data, 145 (91%) had at least one of the following HCV DAA registered: 122 (76%) countries had sofosbuvir-velpatasvir, 61 (38%) had sofosbuvir-velpatasvir-voxilaprevir, 73 (46%) had glecaprevir-pibrentasvir, 68 (43%) had sofosbuvir and daclatasvir, and 126 (79%) had sofosbuvir. Some regions had comparatively fewer DAAs registered than others, e.g., of countries with available information, 43% (3/7) of countries in the Caribbean and 0% (0/3) countries in the Pacific Island States and Territories (figure 1). Among LMICs (n=102), 89 (87%) had at least one HCV DAA registered: 66 (65%) countries had sofosbuvir-velpatasvir, 11 (11%) had sofosbuvir-velpatasvir-voxilaprevir, 21 (21%) had glecaprevir-pibrentasvir, 59 (58%) had sofosbuvir and daclatasvir, and 78 (76%) had sofosbuvir.

Among 160 countries, 109 (68%) had reimbursed at least one DAA: 94 (59%) countries reimbursed sofosbuvir-velpatasvir, 52 (33%) reimbursed sofosbuvir-velpatasvir-voxilaprevir, 65 (41%) reimbursed glecaprevir-pibrentasvir, 43 (27%) reimbursed sofosbuvir and daclatasvir, and 72 (45%) reimbursed sofosbuvir. Some regions had considerably more reimbursement than others, e.g., of countries with available information, 100% (19/19) of countries in Eastern Europe had access to reimbursed DAAs compared to 50% (2/4) of countries in Central Asia and 25% (9/36) in Sub-Saharan Africa (figure 1). Among LMICs (n=102), 53 (52%) had reimbursed at least one DAA: 43 (42%) had reimbursed sofosbuvir-velpatasvir, 9 (9%) had sofosbuvir-velpatasvir-voxilaprevir, 13 (13%) had glecaprevir-pbirentasvir, 35 (34%) had sofosbuvir and daclatsvir, and 41 (40%) had sofosbuvir. A few countries had DAAs reimbursed but were not registered in-country. Sofosbuvir-velpatasvir was reimbursed but not registered in Moldova and the Republic of North Macedonia. Sofosbuvir-velpatasvir-voxilaprevir was reimbursed but not registered in Azerbaijan.

Glecaprevir-pibrentasvir was reimbursed in Azerbaijan and the Cook Islands (provided through an arrangement with New Zealand) but was not registered. Sofosbuvir-daclatasvir was listed as reimbursed but was no longer registered in Ireland, Mexico, Norway, and Svalbard and Jan Mayen.

Among the 109 countries with reimbursed DAAs, 66 (61%) countries had a specialist only restriction, of which nearly half (n=31) were LMICs. 35 (32%) had no restrictions, 6 (6%) had none stated, and two had no information (Albania, Azerbaijan) (figure 2). In some countries, such as Guatemala, general practitioner prescribing was permitted but treatment was only available at public HIV centres managed by HIV specialists. Thus, in practice, DAA prescribing among general practitioners was not common.

Of 109 countries, three (3%) countries (including one LMIC) had liver fibrosis disease stage requirement of ≥F1 (minimal fibrosis or higher), 94 (86%) had no liver fibrosis restriction, 10 (9%) had none stated, and two had no information (Albania, Libya) (figure 3). The three countries with listed fibrosis stage requirements were Latvia (≥F1), Lithuania (≥F2), and Thailand (≥F2). In several countries (e.g., Colombia, Croatia, Eritrea, Mozambique, Peru, Russian Federation, Ukraine, Uzbekistan), written documentation stated that ministries would implement liver disease staging requirements if there was ever a short supply of DAAs and/or they prioritised persons with higher liver disease stage (≥F3) for HCV treatment.

Seven (6%) countries (including four LMICs) had drug use restrictions, 77 (71%) had no drug use restrictions, 22 (20%) had none stated, and three (3%) had no information (Albania, Bolivia, China) (figure 4). There were five (5%) countries (including three LMICs) with alcohol use restrictions, 68 (62%) with no alcohol use restrictions, 32 (29%) with none stated,

and four (4%) with no information (Albania, Bangladesh, Bolivia, China) (figure 5). Restrictions included patient abstinence from drug and/or alcohol use, enrollment in an opioid agonist treatment program, and/or evaluation by a mental health provider prior to DAA initiation (Bosnia and Herzegovina, Brunei Darussalam, Croatia, Guyana, Libyan Arab Jamahiriya, Uruguay; supplementary table 1).

Eight (7%) countries (including 4 LMICs) had HCV retreatment restrictions, 77 (71%) had no restrictions, 21 (19%) had none stated, and three (3%) had no information (Albania, China, Libya) (figure 6). Restrictions included limited retreatment cycles (Commonwealth of Puerto Rico, Taiwan, Turkey) or partially reimbursing retreatment (Republic of Korea). Bosnia and Herzegovina provided retreatment to PWID on a case-by-case basis. Macedonia, Myanmar, and Uruguay did not reimburse retreatment (supplementary table 2). Some country documentation provided clear instructions to practitioners regarding retreatment in the case of virologic failure (e.g., Pakistan, Kazakhstan) but lacked guidance for retreatment in the event of reinfection from high-risk behaviours. Country guidance could also be province-specific, as in the case of Canada, which does not have a national retreatment policy (most nationals had no restrictions to reimbursed retreatment or were on a case-by-case basis). In some countries, while there were no restrictions to retreatment, there were additional patient barriers to care (e.g., in Malta, retreatment was permitted but involved an extended wait time) (supplementary figure 1).

Discussion

In this study, data were retrieved for 160 countries regarding registration, reimbursement, and restrictions of reimbursed DAAs worldwide. 145 (91%) countries had at least one HCV DAA registered and 109 (68%) reimbursed at least one DAA therapy. Among LMICs (n=102), 89 (87%) had at least one DAA registered and 53 (52%) reimbursed at least one DAA therapy. 66 (61%) countries had a prescriber type restriction, three (3%) had liver disease stage restrictions, seven (6%) had drug use restrictions, five (5%) had alcohol use restrictions, and eight (7%) had retreatment restrictions. Despite a recent trend towards removing restrictions to reimbursed DAAs,[14,15,17] more work is needed to increase global access to reach WHO targets.

Our findings suggest suboptimal levels of DAA reimbursement among countries where they are registered: 145 countries (91%) had at least one DAA registered and 109 (68%) reimbursed at least one DAA therapy with considerable variation in regional access. Fewer reimbursed DAAs provided in Central Asia, the Caribbean, Pacific States and Territories, and Sub-Saharan Africa. While the development and approval timelines varied for DAAs – and it is probable that fewer countries would have had newer DAAs – our findings illustrate disparities in reimbursement with LMICs particularly disadvantaged. Our findings also provide a baseline from which further research can explore additional indicators to encapsulate DAA access. For example, some HCV treatment was solely provided in urban-based, specialised HIV centres, and thus, additional research primarily focusing on optimization of DAA implementation is merited.

Our data indicate that prescriber restrictions were the most common DAA restriction. 66 (61%) countries implemented a specialist only prescribing, consistent with findings from a

European study.[14] This restriction reduces the proportion of available prescribers and requires patients to receive treatment from a specialist centre (often hospital-based). This is a major barrier for marginalised population groups (e.g., PWID) who are more likely to experience stigma in healthcare settings and avoid attending hospital-based centres, and for people who reside in remote areas who live farther away from specalists.[5,24] There are some specialist prescribing pathways that seem to elicit minimal patient burden e.g., in Norway, the hospital-based specialist submits an electronic prescription to a community-based practitioner forgoing the need for the patient to attend the hospital. Still, increasing task sharing of HCV testing and treatment to non-specialised centres (e.g., primary care centres) would broaden access.[8,25] A review of 142 studies involving 34 countries found that non-specialists managing HCV-related care achieved comparable HCV cure responses as specialists, providing evidence for task-sharing.[26-28] Practitioners who take on DAA prescribing have also reported professional benefits (e.g., professional fulfillment).[29] Nonetheless, even when countries permit general practitioners to prescribe DAAs, the practice may be uncommon as providers may be unaware of the change in clinical guidelines[25] indicating that ongoing, widespread awareness campaigns are needed.

Of the data available, three countries (3%) required evidence of liver fibrosis as a prerequisite to reimbursed DAAs. The removal or lack of liver disease stage restrictions in most countries – previously nearly three-quarters (74%) of US-states and nearly half (46%) of European countries had fibrosis-stage restrictions[14,15] – is likely the result of reduced DAA price.[30,31] Patients are no longer required to attend an additional appointment to receive a direct liver disease assessment (e.g., transient elastography) prior to DAA initiation unless compensated or decompensated liver cirrhosis is indicated through an indirect liver assessment (e.g., blood test). Allowing indirect liver disease assessments has also meant that LMICs with limited

health budgets and trained personnel – and clinics beyond urban areas – can implement simplified HCV test and treat care models, enhancing patient access to care.[30]

Seven (6%) countries had illicit drug use restrictions and five (5%) had alcohol use restrictions (supplementary table 1). People who use illicit drugs or alcohol can adhere to DAA therapy[32,33] and should be offered HCV treatment without delay in accordance with WHO recommendations.[34] The intention of the listed restriction criteria might be to offer holistic HCV-related care yet these requirements contrast with WHO's call for simplified care models[25] and likely exacerbate health inequities.[35] Such restrictions should be removed. Lastly, of the data available, a sizeable proportion of countries lacked information on drug and alcohol use restrictions. Countries should provide clearer guidance in their national HCV treatment policies and guidelines.

Eight (8%) countries had restrictions on patients accessing HCV retreatment. Compared to retrieving information for other restrictions, retreatment documentation was more challenging to interpret. Country documentation frequently stated that retreatment was permitted for virological failure but retreatment for reinfection due to high risk behaviour was not often stated or evident. A few countries limited retreatment cycles (supplementary table 2).

HCV retreatment information should be stated more clearly in national policies, clinical guidance documents, and health insurance forms. Improved guidance would minimise provider time and administrative burden, make it clearer that retreatment is permitted, and alleviate practitioner hesitations to offer HCV (re)treatment to PWID, who are highly likely to adhere to (re)treatment.[36-39] Timely uptake of (re)treatment will be important for decreasing HCV prevalence and incidence globally.[40,41] Increased coverage of harm reduction services

worldwide[42,43] would permit more integrated HCV-harm reduction services models, helping to increase HCV (re)treatment uptake among PWID.[44,45] Lastly, although some countries in our review permitted retreatment, they did not have many therapies registered and so retreatment options were also limited. Although some preliminary evidence has demonstrated high cure responses (>90%) in LMICs when using second-line HCV DAAs for retreatment, from a health equity lens, our broader goal should be to increase access to sofosbuvir-velapatasvir-voxilaprevir globally.[46]

Compared to other infectious diseases, global leadership and financial backing is lacking for HCV.[47,48] High DAA costs continue to limit access because not all countries have a universal healthcare system willing or able to cover costs, indicating a need for more innovative financing models (e.g., public-private partnerships).[4,48-50] Some countries have the capacity to manufacture their own generic versions of HCV therapies (e.g., China, India, Russia), and notably, some LMICs have widespread access to generics (e.g., $60 USD for sofosbuvir and daclatasvir in Rwanda in 2019).[47] A few LMICs in this study were receiving DAA supply from an international non-governmental organization and/or via funding from the Global Fund, which could become an increasing avenue of HCV-related support.[51] In May 2023, the Clinton Health Access Initiative and The Hepatitis Fund helped to facilitate price agreements with generic manufacturers (Viatris and Hetero) to provide sofosbuvir-daclatasvir to LMICs for $60 USD per treatment course.[51,52] Increased funds and access to generics are promising steps to HCV elimination. Continued monitoring of DAA uptake, preferably as part of national strategies, will be key to track progress towards WHO targets.[47,53]

Our study has limitations. In contrast to research conducted on DAA reimbursement in Canada and Europe[14,17], there was less written documentation available. Some countries,

particularly LMICs, did not have online drug formularies, reimbursement forms, national plans, and/or clinical practice guidelines from which to extract data or these data were from the interferon-based era. Due to poor infrastructure and/or armed conflicts, a few countries had unreliable internet access. Overall, countries had more information on HIV therapies likely due to greater global financing, better data management systems, and in some cases, higher HIV burden.[54] Our data collection pertained to DAA access to persons ≥18 years. Research investigating DAA access for youth and children, who remain largely absent from national plans and strategies is merited (e.g., aged ≥3 years in Guyana's HCV test and treat guidelines).[20] The data collected in this study included DAAs that were subsidised but cost may still be prohibitive for marginalised populations and/or persons residing in LMICs.[23] Primary data collection occurred over a 13-month period, and registration and reimbursement of DAAs may have changed in some countries. However, the Network (n=166) was contacted in June 2023 to re-review all presented data. Study findings cannot speak to implementation of guidance documents among healthcare practitioners (e.g., a restriction could still be applied even if there is no written restriction in place) and how drug criminalization laws[55,56] or other political, economic, and environmental factors affect DAA access. Our research did not report on all DAAs and may underestimate broader access. There were also circumstances in which a provider could technically apply to prescribe a DAA not listed in their country's regulatory agency, and our findings do not capture these circumstances. Additional research on other restrictions to reimbursed DAAs is warranted. This review focused on HCV treatment via public healthcare systems. The role of private healthcare systems in global and national HCV elimination strategies merits further enquiry.[48,57] Akin to other global reviews,[1] we could not retrieve information for all countries. Still, this review has in-country experts (Network) representing nearly every included country, providing a critical resource from which future researchers can collaborate.

This study focused on HCV treatment. Investigating barriers to other pillars of the HCV care cascade will be essential to achieve WHO targets. WHO 2019 estimates indicate that only ~21% of persons with HCV infection have been diagnosed.[58] Availability and access to the newest testing technologies – e.g., point-of-care HCV antibody and HCV RNA testing – remains out of reach in most countries due to high costs of equipment, lack of trained personnel, and lack of country licensing agreements.[4,30,48,59,60] Some countries charge patients for viral load or genotype testing.[47,59] Utilising existing testing infrastructure – e.g., HIV, COVID-19 – could increase HCV testing uptake.[57,61] Similarly, HIV-HCV integrated care has shown to be significantly associated with HCV treatment uptake and is often well received among patients given an existing therapeutic relationship.[26,62,63] HCV self-testing (self-collection) might also broaden testing access and be cost-effective in some situations.[64]

This study provides new HCV registration, reimbursement, and restriction evidence, permitting multi-country analyses and highlighting areas for growth. While the list price of DAAs has become less prohibitive, cost is still a barrier for many countries.[30] Most countries had at least one pan-genotypic DAA registered yet reimbursement was suboptimal overall, particularly in LMICs. Among the reviewed restrictions, non-specialist prescribing is an especially key area for improvement. To meet WHO targets, efforts should be placed on assisting countries in increasing access to DAA reimbursement and removing reimbursement restrictions to assure universal access.

Contributors

All authors contributed to the study design. All authors commented on a study concept sheet constructed by ADM and JG. All authors contributed to data collection. ADM, ARW, AK, NO, VP, and DJ conducted document searches. ADM, ARW, AK, and JG created the Network and collaborated with Network members. ADM, ARW, AK, EBC, AW, GJD, and JG contributed to the data interpretation and data analysis. ADM, ARW, AK, EBC, and JG contributed to the drafting of the manuscript. ADM and JG wrote the original draft manuscript. All authors made substantial contributions to the editing and revising of the manuscript. All authors approved the final version of the manuscript and its decision to submit for publication.

Declaration of interests

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✓Registered
X Not registered
Reimbursed
Not reimbursed
Reimbursement status unknown

		SOF-VEL	SOF-VEL-VOX	GLEC-PIB	SOF-DAC	SOF
Eastern Europe	Armenia*	✓	X	✓	X	X
	Azerbaijan*	✓	X	X	✓	✓
	Belarus*	✓	X	✓	X	✓
	Bosnia & Herzegovina*	✓	X	✓	X	X
	Bulgaria	✓	✓	✓	X	✓
	Croatia	✓	✓	✓	X	✓
	Czech Republic	✓	✓	✓	X	✓
	Estonia	✓	✓	✓	X	X
	Georgia*	✓	X	X	X	✓
	Hungary	✓	✓	✓	X	✓
	Latvia	✓	✓	✓	X	✓
	Lithuania	✓	✓	✓	X	✓
	Moldova*	X	X	✓	✓	✓
	Poland	✓	✓	✓	X	✓
	Romania	✓	✓	✓	X	✓
	Russian Federation	✓	X	✓	✓	✓
	Slovakia	✓	✓	✓	X	✓
	Ukraine*	✓	X	✓	✓	✓
	Svalbard & Jan Mayen	✓	✓	✓	X	✓
Western Europe	Albania*	✓	X	✓	X	X
	Andorra					
	Austria	✓	✓	✓	✓	✓
	Belgium	✓	✓	✓	X	✓
	Denmark	✓	✓	✓	X	✓
	England	✓	✓	✓	X	✓
	Finland	✓	✓	✓	X	✓
	Republic of North Macedonia*	X	X	X	X	X
	France	✓	✓	✓	X	✓
	Germany	✓	✓	✓	✓	✓
	Greece	✓	✓	✓	X	✓
	Iceland	✓	✓	X	X	✓
	Ireland	✓	✓	✓	X	✓
	Italy	✓	✓	✓	X	✓
	Liechtenstein	✓	✓	✓	X	✓
	Luxembourg	✓	✓	✓	X	✓
	Malta	✓	✓	X	X	X

	Monaco					
	Montenegro*	✓	X	✓	X	X
	Netherlands	✓	✓	✓	✓	✓
	Norway	✓	✓	✓	X	✓
	Northern Ireland	✓	✓	✓	X	✓
	Portugal	✓	✓	✓	X	✓
	San Marino					
	Scotland	✓	✓	✓	X	✓
	Serbia*	✓	X	✓	X	✓
	Slovenia	✓	✓	✓	X	✓
	Spain	✓	✓	✓	X	✓
	Sweden	✓	✓	✓	X	✓
	Switzerland	✓	✓	✓	X	✓
	Greenland	✓	✓	✓	X	✓
	Wales	✓	✓	✓	X	✓
East & Southeast Asia	Brunei Darussalam	✓	X	✓	X	X
	Cambodia*	X	X	X	✓	✓
	China*	✓	✓	✓	✓	✓
	DPR Korea*					
	Indonesia*	✓	X	X	✓	✓
	Japan	✓	X	✓	✓	✓
	Lao PDR*	✓	X	X	✓	✓
	Malaysia*	✓	X	X	✓	✓
	Mongolia*	X	X	X	✓	✓
	Myanmar*	✓	X	X	✓	✓
	Republic of Korea	✓	✓	✓	✓	✓
	Philippines*	✓	X	X	✓	✓
	Singapore	✓	✓	✓	X	X
	Taiwan	✓	✓	✓	X	✓
	Thailand*	✓	X	X	X	✓
	Timor Leste*	✓	X	X	X	X
	Viet Nam*	✓	X	X	✓	✓
South Asia	Afghanistan*	X	X	X	✓	✓
	Bangladesh*	✓	X	✓	✓	✓
	Bhutan*	✓	X	X	X	✓
	India*	✓	X	X	✓	✓
	Iran, Islamic Republic*	✓	X	X	✓	✓
	Maldives*	✓	X	X	X	✓
	Nepal*	✓	X	X	X	✓
	Pakistan*	✓	X	X	✓	✓
	Sri Lanka*					
	Kazakhstan*	✓	X	X	✓	✓

Central Asia	Kyrgyzstan*	✓	X	X	✓	✓
	Tajikistan*	✓	X	X	✓	✓
	Turkmenistan*					
	Uzbekistan*	✓	X	X	✓	✓
Caribbean	Antigua & Barbuda					
	Bahamas					
	Barbados					
	Bermuda					
	Commonwealth of Puerto Rico	✓	✓	✓	X	✓
	Cuba*	X	X	X	X	✓
	Dominica*					
	Dominican Republic*	✓	✓	X	✓	✓
	Grenada*					
	Haiti*	X	X	X	✓	✓
	Jamaica*	✓	X	X	X	X
	Saint Kitts & Nevis					
	Saint Lucia*					
	Saint Vincent & Grenadines*	X	X	X	X	X
	Trinidad & Tobago	X	X	X	X	X
Latin America	Argentina*	✓	✓	✓	✓	✓
	Belize*					
	Bolivia*	X	X	X	✓	✓
	Brazil*	✓	✓	✓	✓	✓
	Chile	✓	✓	X	X	X
	Colombia*	✓	X	X	✓	✓
	Costa Rica*					
	Ecuador*	X	X	X	X	✓
	El Salvador*					
	Guatemala*	✓	X	X	X	X
	Guyana*	✓	X	X	✓	✓
	Honduras*					
	Mexico*	✓	X	✓	X	✓
	Nicaragua*					
	Panama*					
	Paraguay*					
	Peru*	✓	X	✓	X	✓
	Suriname*					
	Uruguay	✓	X	✓	✓	✓
	Venezuela*	X	X	X	X	✓
	French Guiana					
North Amer.	Canada	✓	✓	✓	X	✓
	United States	✓	✓	✓	X	✓

Pacific Island States & Territories	American Samoa					
	Cook Islands					
	Fed. States of Micronesia*					
	Fiji*	X	X	X	X	X
	French Polynesia					
	Guam					
	Kiribati*					
	Marshall Islands*					
	Nauru*					
	New Caledonia					
	Palau*					
	Papua New Guinea*	X	X	X	X	X
	Samoa*					
	Solomon Islands*					
	Tonga*	X	X	X	X	X
	Tuvalu*					
	Vanuatu*					
Australasia	Australia	✓	✓	✓	X	X
	New Zealand	✓	✓	✓	X	✓
Middle East & North Africa	Algeria*	✓	X	X	✓	✓
	Bahrain	✓	X	✓	X	✓
	Cyprus	✓	✓	✓	X	✓
	Egypt*	✓	✓	X	✓	✓
	Iraq*					
	Israel	✓	✓	✓	X	X
	Jordan*	✓	X	X	✓	✓
	Kuwait	✓	✓	✓	X	X
	Lebanon*	✓	✓	✓	✓	✓
	Libyan Arab Jamahiriya*	✓	✓	X	✓	✓
	Morocco*	✓	X	X	✓	✓
	Occupied Palestinian Territories*	X	X	X	X	X
	Oman	✓	X	X	✓	✓
	Qatar					
	Saudi Arabia	✓	✓	✓	✓	✓
	Sudan*	X	X	✓	X	X
	Syrian Arab Republic*					
	Tunisia*	X	X	X	X	✓
	Turkey*	X	✓	✓	X	✓
	United Arab Emirates	✓	✓	✓	X	✓
	Yemen*					
	Western Sahara*					
	Angola*	X	X	X	X	X

Sub Saharan Africa	Benin*	✓	X	X	✓	✓
	Botswana*	✓	X	X	X	✓
	Burkina Faso*	✓	X	X	✓	✓
	Burundi*	✓	X	X	✓	✓
	Cameroon*	✓	X	X	✓	✓
	Cape Verde*					
	Central African Republic*					
	Chad*	✓	X	X	✓	✓
	Comoros*	X	X	X	✓	✓
	Cote d'Ivoire*	✓	X	X	X	X
	Dem. Rep. of the Congo*	X	X	X	✓	✓
	Djibouti*					
	Equatorial Guinea*					
	Eritrea*	✓	✓	✓	✓	✓
	Ethiopia*	✓	X	X	✓	✓
	Gabon*	X	X	X	✓	✓
	Gambia*	X	X	X	X	X
	Ghana*	X	X	X	X	X
	Guinea*	✓	✓	✓	✓	✓
	Guinea-Bissau*	✓	X	✓	✓	✓
	Kenya*	✓	X	X	✓	✓
	Lesotho*					
	Liberia*	X	X	X	✓	✓
	Madagascar*	✓	X	X	X	✓
	Malawi*	✓	X	X	✓	✓
	Mali*	X	X	X	X	✓
	Mauritania*	X	X	X	✓	✓
	Mauritius*	✓	X	X	X	X
	Mozambique*	✓	X	✓	✓	✓
	Namibia*	X	X	X	X	✓
	Niger*					
	Nigeria*	✓	X	X	✓	✓
	Republic of the Congo*					
	Rwanda*	✓	✓	X	✓	✓
	Sao Tome & Principe*					
	Senegal*					
	Seychelles					
	Sierra Leone*					
	Somalia*	X	X	X	✓	✓
	South Africa*	✓	X	X	X	X
	Eswatini*	X	X	X	X	X
	Togo*	✓	X	X	✓	✓

	Uganda*	✓	X	X	✓	✓
	United Rep. of Tanzania*	✓	X	X	✓	✓
	Zambia*	X	X	X	✓	✓
	Zimbabwe*	X	X	X	✓	✓
	South Sudan*	X	X	X	X	✓

***Figure 1*. Registered and reimbursed DAAs for HCV infection by country**

SOF=sofosbuvir. VEL=velpatasvir. VOX=voxilaprevir. GLEC=glecaprevir. PIB=pibrentasvir. DAC=daclatasvir. *=Designated as low- and middle-income country or territories as defined by Development Assistance Committee of Official Development Assistance recipients. Effective for reporting on 2022 and 2023 flows. Organisation for Economic Co-operation and Development.

Please note: Figure 1 has been reuploaded into a separate file as requested

***Figure 2*: Prescriber type restrictions for reimbursement of DAAs for patients with HCV infection by country**

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Figure 3: **Liver fibrosis disease stage restriction to reimbursement DAAs for patients with HCV infection by country**

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***Figure 4*: Illicit drug use restrictions to reimbursed DAAs for patients with HCV infection and recent drug dependence by country**

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***Figure 5*: Alcohol use restrictions to reimbursed DAAs for patients with HCV infection and recent alcohol dependence by country**

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***Figure 6*: Retreatment restrictions to reimbursed DAAs for patients with HCV infection by country**

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***Supplementary Table 1*. Criteria for countries that have drug and alcohol use restrictions for HCV DAA therapy**

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***Supplementary Table 2*. Criteria for countries that have retreatment restrictions for HCV DAA therapy**

Please note that this Table has now been reuploaded as a separate Word file as requested

- NO (evidence indicates that restrictions are absent)
- NS (restrictions are not specified; assumed absent)
- YES (evidence indicates that restrictions are present)
- N/A (not applicable; medication not reimbursed)
- NI (no information regarding presence/absence of restrictions)

		Prescriber	Fibrosis stage	Drug use	Alcohol use	Retreatment
Eastern Europe	Armenia*	Yes	No	No	NS	NS
	Azerbaijan*	NI	NS	NS	No	NS
	Belarus*	Yes	No	No	No	No
	Bosnia & Herzegovina*	Yes	No	Yes	Yes	Yes
	Bulgaria	Yes	No	No	No	No
	Croatia	Yes	No	Yes	Yes	No
	Czech Republic	Yes	No	No	No	No
	Estonia	Yes	No	No	No	No
	Georgia*	No	No	No	NS	No
	Hungary	Yes	No	No	No	No
	Latvia	Yes	Yes	No	No	No
	Lithuania	Yes	Yes	No	No	No
	Moldova*	No	No	No	No	No
	Poland	Yes	No	No	No	No
	Romania	Yes	No	No	No	No
	Russian Federation	Yes	No	No	NS	NS
	Slovakia	Yes	No	No	No	No
	Ukraine*	No	No	No	No	No
	Svalbard & Jan Mayen	Yes	No	No	No	No
Western Europe	Albania*	NI	NI	NI	NI	NI
	Andorra	NI	NI	NI	NI	NI
	Austria	Yes	No	No	No	No
	Belgium	Yes	No	No	No	NS
	Denmark	Yes	No	No	No	No
	England	No	No	No	No	No
	Finland	No	No	No	No	No
	Republic of North Macedonia*	Yes	No	Yes	Yes	Yes
	France	No	No	No	No	No
	Germany	No	No	No	No	No
	Greece	Yes	No	No	No	No
	Iceland	Yes	No	No	No	No
	Ireland	No	No	No	No	NS
	Italy	Yes	No	No	No	NS
	Liechtenstein	No	No	No	No	NS
	Luxembourg	Yes	No	No	No	No
	Malta	Yes	No	No	No	No
	Monaco	NI	NI	NI	NI	NI

	Montenegro*	NI	NI	NI	NI	NI
	Netherlands	No	No	No	No	No
	Norway	Yes	No	No	No	No
	Northern Ireland	Yes	No	No	No	No
	Portugal	Yes	No	No	No	NS
	San Marino	NI	NI	NI	NI	NI
	Scotland	No	No	No	No	No
	Serbia*	Yes	NS	NS	NS	No
	Slovenia	Yes	No	No	No	No
	Spain	Yes	No	No	No	No
	Sweden	No	No	No	No	No
	Switzerland	No	No	No	No	NS
	Greenland	Yes	No	No	No	No
	Wales	No	No	No	No	No
East & Southeast Asia	Brunei Darussalam	Yes	No	Yes	No	No
	Cambodia*	N/A	N/A	N/A	N/A	N/A
	China*	Yes	NS	NI	NI	NI
	DPR Korea*	NI	NI	NI	NI	NI
	Indonesia*	Yes	No	NS	NS	No
	Japan	NS	NS	NS	NS	NS
	Lao PDR*	N/A	N/A	N/A	N/A	N/A
	Malaysia*	Yes	No	No	No	NS
	Mongolia*	Yes	No	No	No	No
	Myanmar*	No	No	No	No	Yes
	Republic of Korea	No	NS	No	NS	Yes
	Philippines*	N/A	N/A	N/A	N/A	N/A
	Singapore	Yes	No	NS	NS	No
	Taiwan*	No	No	NS	NS	Yes
	Thailand*	Yes	Yes	No	No	No
	Timor Leste*	Yes	NS	NS	NS	No
	Viet Nam*	Yes	No	No	NS	NS
South Asia	Afghanistan*	No	No	No	No	No
	Bangladesh*	Yes	No	No	NI	No
	Bhutan*	No	No	NS	NS	NS
	India*	No	No	No	No	No
	Iran, Islamic Republic*	Yes	No	No	NS	No
	Maldives*	NI	NI	NI	NI	NI
	Nepal*	N/A	N/A	N/A	N/A	N/A
	Pakistan*	NS	No	No	No	No
	Sri Lanka*	NI	NI	NI	NI	NI
Central Asia	Kazakhstan*	Yes	No	No	No	No
	Kyrgyzstan*	N/A	N/A	N/A	N/A	N/A
	Tajikistan*	N/A	N/A	N/A	N/A	N/A
	Turkmenistan*	NI	NI	NI	NI	NI

	Uzbekistan*	Yes	No	No	No	No
Caribbean	Antigua & Barbuda	NI	NI	NI	NI	NI
	Bahamas	NI	NI	NI	NI	NI
	Barbados	NI	NI	NI	NI	NI
	Bermuda	NI	NI	NI	NI	NI
	Commonwealth of Puerto Rico	No	No	No	No	Yes
	Cuba*	NI	NI	NI	NI	NI
	Dominica*	NI	NI	NI	NI	NI
	Dominican Republic*	Yes	No	NS	NS	No
	Grenada*	NI	NI	NI	NI	NI
	Haiti*	NS	No	No	NS	No
	Jamaica*	N/A	N/A	N/A	N/A	N/A
	Saint Kitts & Nevis	NI	NI	NI	NI	NI
	Saint Lucia*	NI	NI	NI	NI	NI
	Saint Vincent & Grenadines*	N/A	N/A	N/A	N/A	N/A
	Trinidad & Tobago	N/A	N/A	N/A	N/A	N/A
Latin America	Argentina*	No	No	No	No	No
	Belize*	NI	NI	NI	NI	NI
	Bolivia*	Yes	No	NI	NI	No
	Brazil*	No	No	No	No	No
	Chile	Yes	No	NS	NS	NS
	Colombia*	Yes	No	No	No	No
	Costa Rica*	NI	NI	NI	NI	NI
	Ecuador*	Yes	No	No	No	No
	El Salvador*	NI	NI	NI	NI	NI
	Guatemala*	No	No	No	NS	No
	Guyana*	Yes	No	Yes	NS	No
	Honduras*	NI	NI	NI	NI	NI
	Mexico*	No	No	No	No	NS
	Nicaragua*	NI	NI	NI	NI	NI
	Panama*	NI	NI	NI	NI	NI
	Paraguay*	NI	NI	NI	NI	NI
	Peru*	Yes	No	No	No	No
	Suriname*	NI	NI	NI	NI	NI
	Uruguay	Yes	NS	Yes	Yes	Yes
	Venezuela*	N/A	N/A	N/A	N/A	N/A
	French Guiana	NI	NI	NI	NI	NI
North Amer.	Canada	No	No	NS	NS	NS
	United States	No	No	No	No	No
Pacific Island States & Territories	American Samoa	NI	NI	NI	NI	NI
	Cook Islands	No	No	No	No	No
	Fed. States of Micronesia*	NI	NI	NI	NI	NI
	Fiji*	N/A	N/A	N/A	N/A	N/A
	French Polynesia	NI	NI	NI	NI	NI

	Guam	NI	NI	NI	NI	NI
	Kiribati*	NI	NI	NI	NI	NI
	Marshall Islands*	NI	NI	NI	NI	NI
	Nauru*	NI	NI	NI	NI	NI
	New Caledonia	NI	NI	NI	NI	NI
	Palau*	NI	NI	NI	NI	NI
	Papua New Guinea*	N/A	N/A	N/A	N/A	N/A
	Samoa*	NI	NI	NI	NI	NI
	Solomon Islands*	NI	NI	NI	NI	NI
	Tonga*	NI	NI	NI	NI	NI
	Tuvalu*	NI	NI	NI	NI	NI
	Vanuatu*	NI	NI	NI	NI	NI
Australasia	Australia	No	No	No	No	No
	New Zealand	No	No	No	No	No
Middle East & North Africa	Algeria*	Yes	No	No	No	No
	Bahrain	Yes	No	No	No	No
	Cyprus	NI	NI	NI	NI	NI
	Egypt*	NS	No	NS	NS	No
	Iraq*	NI	NI	NI	NI	NI
	Israel	No	No	NS	NS	NS
	Jordan*	NS	No	NS	NS	No
	Kuwait	Yes	No	No	No	No
	Lebanon*	NI	NI	NI	NI	NI
	Libyan Arab Jamahiriya*	Yes	NI	Yes	Yes	NI
	Morocco*	Yes	NS	No	NS	No
	Occupied Palestinian Territories*	N/A	N/A	N/A	N/A	N/A
	Oman	Yes	No	No	No	No
	Qatar	NI	NI	NI	NI	NI
	Saudi Arabia	Yes	No	NS	NS	No
	Sudan*	N/A	N/A	N/A	N/A	N/A
	Syrian Arab Republic*	NI	NI	NI	NI	NI
	Tunisia*	Yes	No	NS	NS	NS
	Turkey*	Yes	No	NS	NS	Yes
	United Arab Emirates	Yes	No	No	No	No
	Yemen*	NI	NI	NI	NI	NI
	Western Sahara*	NI	NI	NI	NI	NI
Sub Saharan Africa	Angola*	N/A	N/A	N/A	N/A	N/A
	Benin*	Yes	No	NS	NS	No
	Botswana*	NI	NI	NI	NI	NI
	Burkina Faso*	N/A	N/A	N/A	N/A	N/A
	Burundi*	N/A	N/A	N/A	N/A	N/A
	Cameroon*	No	No	No	No	No
	Cape Verde*	NI	NI	NI	NI	NI
	Central African Republic*	NI	NI	NI	NI	NI

Chad*	N/A	N/A	N/A	N/A	N/A
Comoros*	N/A	N/A	N/A	N/A	N/A
Cote d'Ivoire*	N/A	N/A	N/A	N/A	N/A
Dem. Rep. of the Congo*	N/A	N/A	N/A	N/A	N/A
Djibouti*	NI	NI	NI	NI	NI
Equatorial Guinea*	NI	NI	NI	NI	NI
Eritrea*	Yes	No	NS	NS	NS
Ethiopia*	N/A	N/A	N/A	N/A	N/A
Gabon*	No	No	No	No	No
Gambia*	N/A	N/A	N/A	N/A	N/A
Ghana*	N/A	N/A	N/A	N/A	N/A
Guinea*	No	NS	NS	NS	No
Guinea-Bissau*	N/A	N/A	N/A	N/A	N/A
Kenya*	NS	NS	No	NS	NS
Lesotho*	NI	NI	NI	NI	NI
Liberia*	N/A	N/A	N/A	N/A	N/A
Madagascar*	N/A	N/A	N/A	N/A	N/A
Malawi*	N/A	N/A	N/A	N/A	N/A
Mali*	NI	NI	NI	NI	NI
Mauritania*	NI	NI	NI	NI	NI
Mauritius*	Yes	No	NS	No	No
Mozambique*	Yes	No	No	NS	NS
Namibia*	NI	NI	NI	NI	NI
Niger*	NI	NI	NI	NI	NI
Nigeria*	N/A	N/A	N/A	N/A	N/A
Republic of the Congo*	N/A	N/A	N/A	N/A	N/A
Rwanda*	No	No	NS	NS	No
Sao Tome & Principe*	NI	NI	NI	NI	NI
Senegal*	N/A	N/A	N/A	N/A	N/A
Seychelles	NI	NI	NI	NI	NI
Sierra Leone*	N/A	N/A	N/A	N/A	N/A
Somalia*	N/A	N/A	N/A	N/A	N/A
South Africa*	N/A	N/A	N/A	N/A	N/A
Eswatini*	N/A	N/A	N/A	N/A	N/A
Togo*	N/A	N/A	N/A	N/A	N/A
Uganda*	N/A	N/A	N/A	N/A	N/A
United Rep. of Tanzania*	N/A	N/A	N/A	N/A	N/A
Zambia*	N/A	N/A	N/A	N/A	N/A
Zimbabwe*	N/A	N/A	N/A	N/A	N/A
South Sudan*	N/A	N/A	N/A	N/A	N/A

***Supplementary Figure 1*. Restrictions to reimbursed DAAs for HCV infection by country**

***Please note: Supplementary Figure 1 has been reuploaded into a separate file as requested**=**Designated as low- and middle-income country or territories as defined by Development Assistance Committee of Official Development Assistance recipients. Effective for reporting on 2022 and 2023 flows. Organisation for Economic Co-operation and Development.

Appendix

Global HCV and HIV Treatment Restrictions Group (Network): Name and Affiliation

Please note that the Appendix has now been supplied as a separate, single PDF file as requested

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