Maintenance Level

M2-AH Hepatitis C Adjustment – Medical Assistance

Agency Recommendation Summary Text

The Health Care Authority (HCA) requests $113,796,000 ($21,454,000 GF-State) in the 2017-2019 biennium to align with projected costs to treat the hepatitis C virus (HCV) in the medical assistance population for fiscal years 2018 and 2019. Changes in treatment costs are driven by shifts in utilization and unit costs, as well as court-mandated changes implemented in June 2016.

Fiscal Summary

Operating Expenditures	FY 2018	FY 2019	FY 2020	FY 2021
Fund 001-1 GF-State	$12,390,000	$9,064,000	$18,172,000	$31,097,000
Fund 001-C GF-Federal	$52,520,000	$39,822,000	$56,517,000	$94,722,000
Total Cost	**$64,910,000**	**$48,886,000**	**$74,689,000**	**$125,819,000**

Staffing	FY 2018	FY 2019	FY 2020	FY 2021
FTEs	0.0	0.0	0.0	0.0

Revenue	FY 2018	FY 2019	FY 2020	FY 2021
Fund 001-C GF-Federal	$52,520,000	$39,822,000	$56,517,000	$94,722,000
Total Revenue	**$52,520,000**	**$39,822,000**	**$56,517,000**	**$94,722,000**

Object of Expenditure	FY 2018	FY 2019	FY 2020	FY 2021
Obj. N – Client Services	$64,910,000	$48,886,000	$74,689,000	$125,819,000

Package Description

According to the Center for Disease Control (CDC), hepatitis C is a chronic viral infection of the liver that affects approximately one percent of the U.S. population, or about three million people nationwide. In Washington State, 75,000 to 100,000 people are estimated to be infected with chronic hepatitis C. If untreated, about 35 percent of patients infected will develop chronic liver disease, cirrhosis, or liver cancer over a time span of 20 to 30 years.

Liver scarring (i.e. fibrosis) caused by hepatitis C is categorized along a continuum, from absent (F0) to severe (F4, which equates to cirrhosis). The more severe a person's fibrosis, the more likely they are to develop complications, and possibly die of their disease.

Advances in the treatment of hepatitis C have led to the availability of highly effective and safe medications that are administered orally either once or twice daily, for a span of eight to 24 weeks, depending on the genotype and severity of the disease. These medications are cost-effective at a population level as measured by the cost per

quality adjusted life year gained. Although the dollar cost of treating a single individual (the Average Wholesale Price for a treatment course is approximately $85,000 to $95,000) is high, additional medications to treat hepatitis C have been approved by the federal Food and Drug Administration (FDA), resulting in price competition in the market place. Albeit still expensive, these treatments are now much more affordable.

In 2015, the HCA was funded for a treatment policy that used fibrosis score as a component to determine treatment for clients. This policy was created to ensure that scarce state resources were focused to treat HCV patients who were at the highest risk for liver-related complications. However, as of May 27, 2016, per a preliminary injunction, the HCA is now mandated to stop using fibrosis score as a component to determine treatment for its HCV treatment policy. Current funding to treat HCV is based on only providing treatment to HCV patients with a fibrosis score of F3 or higher. Increased funding is needed to comply with the court order, which is to cover the costs of these treatments for HCV patients at all fibrosis levels.

This funding request includes two components: 1) the difference between the updated cost model and current funding, both assuming the previous F3-or-higher fibrosis policy, and 2) the additional cost to comport with the judicial mandate to cover HCV patients with fibrosis scores of F2 and lower.

Krista Umejesi, Financial Services: 360.725.1363 or krista.umejesi@hca.wa.gov

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Decision Package Justification and Impacts

Performance Measure Detail:

Activity Inventory

H005 HCA National Health Reform
H011 HCA All Other Clients – Fee for Service – Mandatory Services

What specific performance outcomes does the agency expect?

The HCA expects to continue to provide access to quality health care by treating to approximately eight thousand low-income individuals infected with HCV in the State of Washington over the course of the biennium. The new treatment options available are able to achieve a sustained virological response (SVR) in 90 to 100 percent of clients with little to no side effects. Those with a SVR are far less likely to see the HCV progress to advanced liver disease (i.e. cirrhosis or liver cancer) or experience other complications associated with hepatitis C infection, including death.

What alternatives were explored by the agency and why was this option chosen?

The HCA originally implemented a treatment policy which used fibrosis score as a component to determine treatment. The recent court order removes this component of the treatment policy and limits the alternatives and options available to the HCA.

What are the consequences of not funding this request?

Without the additional resources requested in this request, the HCA will not have sufficient funding to provide access to vital medical services to Washington's clients as required by the May 27, 2016 injunction.

Washington State Health Care Authority

How has or can the agency address the issue or need in its current appropriation level?

The current funding is not sufficient to support the coverage level required by the court order. The HCA cannot absorb the increased cost within its existing resources.

Provide references to any supporting literature or materials:

http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm

https://www.uptodate.com/contents/treatment-regimens-for-chronic-hepatitis-c-virus-genotype-1-infection-in-adults

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Base Budget

If the proposal is an expansion or alteration of a current program or service, provide information on the resources now devoted to the program or service.

Based on carry forward level, the HCA budget currently contains $161.7 million ($42.3 million GF-State) to cover treatments for Hepatitis C patients through its Medicaid program. For fiscal year 2016, an average of 471 Medicaid clients received these treatments in a month, for a total cost (net estimated rebates) over fiscal year 2016 of $93 million ($19.5 million GF-State).

Expenditure, FTE and Revenue Assumptions, Calculations and Details:

The primary driver in projected hepatitis C drug expenditures for the 2017-2019 biennium is the number of clients expected to come into care. Prior to June 2016, the HCA was able to review about 300 requests for treatment per month, half of which were denied due to low fibrosis levels; however, in removing the fibrosis level requirement the HCA anticipates the number of requests reviewed to stay at 300 per month, 150 for F3 or higher and 150 for the added group of F0 to F2. However, instead of 50 percent approval rate, the revised model assumes 99 percent of those who apply for treatment will be approved for treatment in the month they apply starting June 2016. Despite removing the fibrosis level requirement, it is still necessary to review each case. The treatment is not auto-approved. There are also other requirements, such as chronicity and the absence of other contraindications that must also exist. The review also approves the drug type and length of treatment as the best course of action for the case.

A client that is approved for treatment may not necessarily begin treatment in that same month, as there is often a lag between the date of approval and claim date (starting treatment). The projected number of clients that enter treatment in a month is based on a lag triangle created by the average lag between prior authorization date and first claim date for clients approved for treatment January 2015 to June 2016 (in the months for which actual data is available, the actual number of clients that entered treatment in a month is used instead).

Population prevalence rates are based on estimates made by Research and Data Analysis (RDA) at the Department of Social and Health Services (DSHS) that used published data on populations similar to the Medicaid population. (The prevalence of hepatitis C in the general U.S. population is estimated to be 1.0 to 1.3 percent; however, the Medicaid population is enriched with risk factors for hepatitis C).

Costs reflected in this request are based on a "best guess" estimate on utilization. A calculation of the HCA's high-end estimate (worst case scenario), which is $200.1 million ($41.4 million GF-State) in the 2017-2019 biennium, is included in the accompanying backup document.

Breakdown of Components

1) Updated Estimate – Fibrosis F3 or higher: Reduction of $70.0 million ($21.1 million GF-State)
2) New Estimate – Fibrosis F2 and lower: Increase of $183.8 million ($42.5 million GF-State)

Impacts to Communities and Other Agencies

Fully describe and quantify expected impacts on state residents and specific populations served.

The funding requested in this proposal shall allow the HCA to continue to provide access to quality health care to approximately eight thousand low-income individuals in the State of Washington over the course of the 2017-2019 biennium. The state's Medicaid programs are entitlements, and therefore Washington State must provide access to such services to any resident who applies and is determined financially and medically eligible. This request allows the HCA to comply with the court order and provide hepatitis C treatments that will directly impact the health and well-being of its medical assistance clients.

What are other important connections or impacts related to this proposal?

Does this request have:

Regional/county impacts?	Yes ☒ No ☐
Other local government impacts?	Yes ☒ No ☐
Tribal government impacts?	Yes ☒ No ☐
Other state agency impacts?	Yes ☒ No ☐

Does this request:

Have any connection to Puget Sound recovery?	Yes ☐ No ☒
Respond to specific task force, report, mandate or executive order?	Yes ☒ No ☐
Contain a compensation change?	Yes ☐ No ☒
Require a change to a collective bargaining agreement?	Yes ☐ No ☒
Create facility/workplace needs or impacts?	Yes ☐ No ☒
Contain capital budget impacts?	Yes ☐ No ☒
Require changes to existing statutes, rules or contracts?	Yes ☒ No ☐

Washington State Health Care Authority

Have any relationship to or result from litigation?	Yes ☒ No ☐

If "Yes" to any of the above, please provide a detailed discussion of connections/impacts.

The May 27, 2016 injunction requires the HCA to provide coverage for prescription medications to treat hepatitis C virus without regard to fibrosis score.

The injunction and the subsequent policy change by the HCA may affect other state agencies such as: the Department of Corrections, the DSHS, and Public Employees Benefits, by the precedent it is setting in covering these high cost treatments. It may have a positive impact for regional/county, local, and tribal governments by increasing the health of those being treated.

Information Technology (IT)

Does this request include funding for any IT-related costs, including hardware, software, services (including cloud-based services), contracts or IT staff?

☒ No 

☐ Yes Continue to IT Addendum below and follow the directions on the bottom of the addendum to meet requirements for OCIO review.)