



THE STATE
of **ALASKA**
GOVERNOR BILL WALKER

Department of
Health and Social Services

DIVISION OF HEALTH CARE SERVICES
PHARMACY & ANCILLARY SERVICES UNIT

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September 22, 2017

Re: Clinical Criteria for Use – Hepatitis C Direct Acting Antiviral Agents

Dear Pharmacists, Prescribers, and Members:

On September 1, 2017, the Division of Health Care Services posted proposed Clinical Criteria for Use for Hepatitis C Direct Acting Antiviral Agents on the following sites:

<http://manuals.medicaidalaska.com/docs/updates.htm>
<http://manuals.medicaidalaska.com/docs/ramsgs.htm>
<http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx>
http://dhss.alaska.gov/dhcs/Pages/pdl/drugutilizb_pdl.aspx

The proposed criteria were reviewed at the Drug Utilization Review (DUR) Committee meeting on Friday, September 15 [<http://notice.alaska.gov/186760>; 7 AAC 120.120]. The Committee affirmed the proposed Clinical Criteria for Use for Hepatitis C Direct Acting Antiviral Agents (DAA), to include selection of a preferred product, and approved the criteria with an effective date of October 1, 2017 [7 AAC 105.130; 42 USC 1396r-8]. The Committee's unanimous decision was rendered following significant review of the clinical evaluation of the various products available to include efficacy and safety profiles; pharmacy reimbursement projections based on a population health model; cost effectiveness; fraud, waste, and abuse considerations; rise in drug resistant virus variants; federal funding; and impact to the financial integrity of the Alaska Medicaid Pharmacy program [7 AAC 105.130; 7 AAC 120.120].

During the meeting the Committee considered public comment that was received. Below is a synopsis of the questions and concerns posed.

1. Will patients with a Metavir fibrosis score of 0 or 1 without evidence of disease progression be approved for treatment with the selected preferred agent listed in the criteria?

Yes. The new criteria effective October 1, 2017 includes a public health population approach in addition to prioritizing treatment of individuals at most immediate risk of disease progression. While the CDC notes that not all individuals who have chronic hepatitis C infection will develop long-term morbidity from the virus, efforts to decrease the presence of the virus in the general population may help minimize the overall risk of spread of the virus.

<https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section1>

Patients with a Metavir fibrosis score of 0 or 1 will be approved for treatment with the preferred agent provided all other criteria for approval are met, including a patient readiness assessment and signed patient attestation that affirms patient agreement to complete treatment course and an understanding of the risks of reinfection and contributors of liver damage. Prescribers are encouraged to refer patients to the Alaska Medicaid Coordinated Care Initiative Program (AMCCI) in the following circumstances: (1) patients who may need assistance with connecting to substance use treatment or (2) patients who have other treatment readiness concerns that may impact success. Information on the AMCCI program may be found here: <http://dhss.alaska.gov/dhcs/Pages/amcci/members.aspx>. Members may also self-refer. A form is available on the website or the member may call MedExpert at 1.800.999.1999.

2. What factors did Alaska Medicaid use to make a selection of the preferred agent?

The Alaska Medicaid Drug Utilization Review Committee considered the efficacy and safety profiles of available FDA-approved direct acting antiviral agents for the hepatitis C virus; pharmacy reimbursement projections based on a population health model; cost effectiveness; fraud, waste, and abuse considerations; rise in drug resistant virus variants; federal funding; and impact to the financial integrity of the Alaska Medicaid Pharmacy program.

3. What product was selected as the preferred agent?

Mavyret™ (glecaprevir/pibrentasvir), an HCV NS3/4A protease inhibitor and an HCV NS5A inhibitor

4. Is the treatment length of Mavyret™ longer than other available products?

For most patients without cirrhosis (approximately 80%) who have not tried other products, the FDA-approved label supports an 8-week treatment duration which is shorter than some of the other therapeutically equivalent products.

Patients with genotype 3 with or without cirrhosis who were treated with peg-interferon and ribavirin previously will need 16 weeks of treatment.

In general, treatment-naive patients with cirrhosis will require 12 weeks of treatment.

Refer to page 3 of the criteria and the FDA-approved package insert for other specific treatment lengths.

5. What do I do if my patient has an absolute contraindication to the preferred agent?

Prescribers may request authorization for an alternate FDA-approved direct acting antiviral agent that is FDA-approved with the labeled indication for that patient. Prescribers should refer to page 3 of the new criteria for specifics about alternate agents.

6. My patient is between the ages of 12 and 18. Mavyret™ is not currently FDA-approved for this age range; what agent would be approved?

Alaska Medicaid will authorize utilization of a direct acting antiviral product that is FDA-approved to treat patients from age 12 up to 18.

7. Will patients who have been started on one product be required to change to the new preferred product starting Oct 1, 2017?

No. Patients started on a particular agent prior to October 1 will be allowed to finish their full treatment course with the drug product they started.

8. The efficacy of the selected FDA-approved preferred product is insufficiently proven compared to other commonly prescribed FDA-approved products and is not reflected in the AASLD/IDSA HCV Guidance.

Clinical trials used to support FDA-approval of Mavyret™ demonstrated SVR12 rates between 95% and 100% depending on the treatment subpopulation. SVR12, sustained virologic response, means that there is no detectable virus in the blood at 12-weeks after finishing a treatment course. This marker is used to evaluate success of the treatment.

At the time of the DUR Committee's review on September 15, the AASLD/IDSA guidance had not yet incorporated the two new DAAs approved by the FDA in July and August. The AASLD/IDSA "HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C" document was updated on September 21, 2017 and supported glecaprevir/pibrentasvir (Mavyret™) as a recommended regimen for the most common treatment subpopulations we have seen in Alaska Medicaid – treatment naïve and treatment experienced with peg-interferon and ribavirin. These recommendations were given 'IA' and 'IB' evidence ratings in the guidance. The updated AASLD/IDSA guidance document may be retrieved from the following link: http://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/HCVGuidance_September_21_2017_a.pdf

9. If Medicaid programs are able to negotiate supplemental rebates, why does it matter what the pharmacy reimbursement cost is?

Alaska Medicaid reimburses pharmacies on a fee-for-service basis. When a pharmacy dispenses a medication to a patient, Alaska Medicaid reimburses the pharmacy provider based on the actual acquisition cost of the drug product plus a professional dispensing fee. The actual acquisition cost of the drug product is what it costs the pharmacy to procure the drug product. For HCV DAA drug products with a National Average Drug Acquisition Cost (NADAC), the ingredient cost reimbursement will not exceed the lesser of the NADAC, billed amount, or the Wholesale Acquisition Cost (WAC) plus 1% [<https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html>]. For HCV DAA drug products without a NADAC, the ingredient cost reimbursement will not exceed the lesser of the billed amount or the WAC + 1%. [7 AAC 145.400]

Negotiated rates are obtained through a supplemental rebate process based on preferred product designation. Pharmacies are first reimbursed at the actual acquisition cost and the prescriptions that are reimbursed within a given quarter (3 month period) are submitted on invoices to manufacturers no later than 60 days from the end of the quarter. Manufacturers remit federal rebate payments within 30 days. Additional time is allowed for supplemental rebate processing. Therefore, prescriptions that are reimbursed at the beginning of an invoice quarter may not result in rebate payments for almost 6 months.

Based on epidemiological data, it is estimated that there are between 7,500 and 10,000 individuals in Alaska who are chronic carriers of the hepatitis C virus. Exact prevalence data is not available as not all individuals are routinely tested.

The Drug Utilization Review Committee considered the following scenario:

If the Medicaid Pharmacy program reimbursed pharmacies for an HCV DAA treatment course for 10 new individuals each day over 180 days, this would represent treatment for approximately one-fourth to one-fifth of the estimated individuals living with chronic HCV in Alaska.

If all 1,800 of those new individuals were treated with the first FDA-approved single tablet pangenotypic DAA, pharmacy reimbursement payments by the Alaska Medicaid Pharmacy program during that six month period could exceed \$100 million dollars.

Comparatively, if all 1,800 of those individuals were treated with the proposed preferred product, Mavyret™, a pangenotypic DAA approved by the FDA in August 2017, reimbursement by the Alaska Medicaid Pharmacy program within that same 6 month period could result in approximately \$40-50 million dollars in payments to pharmacies.

10. If Alaska Medicaid did not select Mavyret™ as the preferred product for the treatment of chronic hepatitis C virus, could the program still remove the prioritization requirement from the existing criteria and maintain the financial integrity of the program?

No. Alaska Medicaid would not have sufficient spending authority to cover the high reimbursement costs of other therapeutically equivalent products. The high upfront reimbursement costs of other therapeutically equivalent products without prioritization would jeopardize the State's abilities to reimburse pharmacies for other medically necessary pharmacy services (such as antibiotics, hemophilia factor products, diabetic agents, cystic fibrosis agents, autoimmune products, etc.).

To honor the proposed start date for the new criteria posted on September 1 and approved by the Committee on September 15, the new criteria will become effective on October 1, 2017. The current criteria with an effective date of July 1, 2016 will sunset on Tuesday, October 31, 2017. During this time overlap, prescribers may utilize preferred agents from either concurrently effective criteria.

- If a patient has a Metavir fibrosis score of F2 – F4 between October 1 and October 31, 2017, the prescriber may utilize either set of criteria.
- If the patient has a Metavir fibrosis score of F0 – F1, the patient would qualify under the new criteria with the effective date October 1, 2017.
- On November 1, 2017 and thereafter, the only criteria in effect will be the new criteria with the effective date of October 1, 2017 regardless of Metavir fibrosis score.

All criteria documents are available on the following website:

<http://dhss.alaska.gov/dhcs/Pages/pharmacy/medpriorauthoriz.aspx>

You may contact Erin Narus at erin.narus@alaska.gov or 907.334.2425 with any questions or comments.