

Hepatitis C: State of Medicaid Access Report Card

Puerto Rico



Grade	Summary
<p style="text-align: center; font-size: 2em; font-weight: bold;">D</p>	<p>Liver Damage (Fibrosis) Restrictions: Puerto Rico does not have any liver damage requirements.</p> <p>Sobriety Restrictions: Puerto Rico requires six months' sobriety from alcohol and substance use.</p> <p>Prescriber Restrictions: Puerto Rico requires consultation with certain specialists. Mono-infected and co-infected patients are approved for treatment through different processes either by the Department of Health or the AIDS Drug Assistance Program (ADAP). The process is complicated and not transparent.</p> <p>Recommendations to Improve Patient Access:</p> <ul style="list-style-type: none"> • Remove the onerous sobriety and prescriber approval processes. • Provide transparency regarding access to hepatitis C medications by posting program criteria and requirements on the hepatitis C program website. <p><i>Grade Rationale: Puerto Rico's Department of Health has excluded hepatitis C coverage from Mi Salud, the Managed Care Organization (MCO) program that covers most Medicaid beneficiaries. The Department of Health created a separate program to provide treatment access for patients with hepatitis C that extends beyond Medicaid. Liver damage restrictions have been eliminated but there is still an unacceptable six months' sobriety requirement. Although prescriber requirements are less stringent, the process to secure authorization for treatment is somewhat complicated and arduous.</i></p>

Background

As of June 2015, 1,671,657 people were enrolled in Medicaid and Children's Health Insurance Program (CHIP) in Puerto Rico.¹ The Medicaid program is part of a larger public government healthcare delivery system that provides care to most of the island's population. The Puerto Rico Department of Health is a single state agency, which has a cooperative agreement with the Puerto Rico Health Insurance Administration (PRHIA) also known as Administracion de Seguros Salud de Puerto Rico (ASES).² ASES implements and administers the island-wide health insurance system.³ Approximately half of Puerto Rico's 3.5 million residents depend on the public health system for their medical care.⁴ All beneficiaries are enrolled in a Managed Care Organization (MCO) that is contracted for the service region where they reside.⁵ There are nine geographic regions served by four MCO plans: MultiHealth PSG, Molina Healthcare, Triple-S and First Medical.⁶ Puerto Rico's MCO program is known as *Mi Salud*.⁷ However, hepatitis C treatment is carved out of *Mi Salud*. The Puerto Department of Health, AIDS and Communicable Diseases (OCASET) created a program to treat hepatitis C. The initial pilot phase required patients to be co-infected with HIV and have severe liver damage (F3 or greater), pre- or post-transplant or present other hepatic manifestations, and six months' abstinence from alcohol and substance use to qualify for treatment.⁸ OCASET has since expanded the hepatitis C pilot project and the treatment program is in Phase 2.⁹

State of Medicaid Hepatitis C Treatment Access

Access to hepatitis C treatment is restricted in Puerto Rico. The Puerto Department of Health, AIDS and Communicable Diseases (OCASET) initiated a Pilot Treatment Program from September 1, 2015 through August 31, 2016 through the AIDS Drug Assistance Program (ADAP).¹⁰ Patients were treated at three selected clinics in San Juan, Ponce and Mayaguez.¹¹ Puerto utilized ADAP funds and the provider education infrastructure to provide clinical information for the treatment and management of patients.¹² Puerto Rico also used ADAP to identify eligible patients. Only co-infected individuals qualified for treatment.¹³ The first pilot program targeted co-infected patients with severe liver damage (F3 or greater), pre- and post-transplant or who had other hepatic manifestations.¹⁴ Patients also had to be on HIV therapy for at least six months, have control of other comorbid conditions, be clinically stable, and be abstinent from alcohol and other substance use for at least six months.¹⁵ The pilot program did not include prescriber requirements.¹⁶ Additionally, the patients could only receive treatment at three clinics.¹⁷ Results of the pilot program were as follows: 116 individuals were treated (38 women/78 men) who ranged from 23 to 71 years.¹⁸ Eighty-seven percent were Genotype 1.¹⁹

At the conclusion of the pilot phase, Puerto Rico evaluated the program and began a Phase 2 Project. The Phase 2 Project aims to expand both the number and location of clinics where patients are treated and the types of patients who could qualify for treatment. Phase 2 has the following coverage criteria: individuals without health insurance, ADAP beneficiaries or individuals enrolled in Government's Health Care Plan (Plan de Salud del Gobierno)²⁰ which includes Medicaid enrollees, state employees among others.²¹ If a beneficiary receives care through a private health care plan and is not eligible for ADAP, the patient could qualify for co-payment support or another program.²² To qualify for treatment in the program, the prescriber must conduct and submit the patient's medical history, submit a *Referido Control Para*

Manejo y Tratamiento Hepatitis C form, a *Solicitud Para Pre-Autorizacion de Pruebas Especiales de Hepatitis C (VHC)* (Prior Authorization Form) and required laboratory testing including hepatitis C RNA, genotyping, liver disease progression testing among others.²³ The request must be submitted to OCASET if the patient is mono-infected and to ADAP if the individual is co-infected and qualifies for the ADAP program.²⁴ Additionally, the health care provider must consult with the following specialists as necessary: gastroenterologist, nephrologist, endocrinology, mental health and cardiologist.²⁵ OCASET designated five clinics to provide treatment for hepatitis C in San Juan, Ponce, Mayaguez, Bayamon and Caguas.²⁶ Dr. Ruth Soto is designated to review requests for co-infected patients participating in ADAP.²⁷

Co-infected individuals enrolled in ADAP have access to the following Direct-Acting Antiviral (DAA) regimens: Harvoni, Viekira XR, Sovaldi, Daklinza and Zepatier.²⁸ Formulary or preferred drug information is not available for the patients receiving care through the Department of Health.

Liver Damage (Fibrosis) Restrictions

In Phase 2, OCASET does not impose liver disease requirements.²⁹ Patients who meet the other criteria can qualify for treatment at any stage of disease.³⁰

Sobriety Restrictions

In Phase 2, OCASET requires six months' abstinence from alcohol and substance use.³¹ Additionally, if a patient is actively using alcohol or substances then the patient must be enrolled in a rehabilitation program and can qualify after the individual has demonstrated at least six months of sobriety.³²

Prescriber Restrictions

In Phase 2, OCASET requires the prescriber to consult with following specialists as necessary: gastroenterologist, nephrologist, endocrinology, mental health and cardiologist.³³ Additionally, for mono-infected individuals, treatment is provided at only five designated OCASET clinics in San Juan, Ponce, Mayaguez, Bayamon and Caguas.³⁴ Co-infected individuals who qualify for ADAP receive care through that program.³⁵

Points of Contact for Questions & Concerns about Puerto Rico's State of Medicaid Hepatitis C Access

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¹ Monthly Medicaid and CHIP Enrolment Data, Puerto Rico, By-State, Medicaid.gov (Accessed July 2017): <https://www.medicaid.gov/medicaid/by-state/puerto-rico.html>

² Ibid. Monthly Medicaid and CHIP Enrolment Data, Puerto Rico, By-State, Medicaid.gov

³ Ibid. Monthly Medicaid and CHIP Enrolment Data, Puerto Rico, By-State, Medicaid.gov

⁴ Ibid. Monthly Medicaid and CHIP Enrolment Data, Puerto Rico, By-State, Medicaid.gov

⁵ Ibid. Monthly Medicaid and CHIP Enrolment Data, Puerto Rico, By-State, Medicaid.gov

⁶ Administracion de Seguros Salud de Puerto Rico (ASES), MCOs Por Region (Accessed July 2017): <http://www.medicaid.pr.gov/Proveedores.aspx>

⁷ Annie L. Mach, Congressional Research Service, *Puerto Rico and Health Care Finance: Frequently Asked Questions*, June 20, 2016 (Accessed July 2017): <https://www.fas.org/sgp/crs/row/R44275.pdf>

⁸ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

⁹ Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET, Pacientes Co-Infectados VIH/VHC, OCASET/Ryan White Part B: ADAP, September 1, 2015 – August 31, 2016 (Accessed July 2017)

¹⁰ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹¹ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹² Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹³ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹⁴ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹⁵ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹⁶ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹⁷ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹⁸ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

¹⁹ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

²⁰ Elegibilidad (Eligibility), Plan de Salud del Gobierno de Puerto Rico, Administracion de Seguros Salud de Puerto Rico (ASES) (Accessed July 2017): <http://www.firstmedicalpsg.com/index.php/es/elegibilidad>

²¹ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET; See also: Manual de Procedimiento para la Prestacion de Servicios Proyecto Piloto, Manejo Clinico y Tratamiento de Hepatitis C, Segunda Fase, Secretaria Auxiliar de Salud Familiar y Servicios Integrados, Oficina Central de Asuntos del SIDA y Enfermedades Transmisibles (OCASET), Programa de Hepatitis Virales, Revision: September 30, 2016

²² Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET; See also: Manual de Procedimiento para la Prestacion de Servicios Proyecto Piloto, Manejo Clinico y Tratamiento de Hepatitis C, Segunda Fase

²³ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET; See also: Manual de Procedimiento para la Prestacion de Servicios Proyecto Piloto, Manejo Clinico y Tratamiento de Hepatitis C, Segunda Fase

²⁴ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET; See also: Manual de Procedimiento para la Prestacion de Servicios Proyecto Piloto, Manejo Clinico y Tratamiento de Hepatitis C, Segunda Fase

²⁵ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

²⁶ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

²⁷ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET; See also: Manual de Procedimiento para la Prestacion de Servicios Proyecto Piloto, Manejo Clinico y Tratamiento de Hepatitis C, Segunda Fase, Secretaria Auxiliar de Salud Familiar y Servicios Integrados, Oficina Central de Asuntos del SIDA y Enfermedades Transmisibles (OCASET), Programa de Hepatitis Virales, Revision: September 30, 2016

²⁸ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

²⁹ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

³⁰ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

³¹ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

³² Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

³³ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

³⁴ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

³⁵ Ibid. Resultados de la Primera Fase del Proyecto Piloto, Proyecto Piloto Para el Tratamiento de Hepatitis C: OCASET

³⁶ Directorio, Departamento de Salud, Gobierno de Puerto Rico (Accessed July 2017): <http://www.salud.gov.pr/Dept-de-Salud/Pages/Directorio.aspx>

³⁷ Ibid. Directorio, Departamento de Salud, Gobierno de Puerto Rico