## DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-14-26 Baltimore, Maryland 21244-1850



## **Center for Medicaid and CHIP Services**

## Disabled and Elderly Health Programs Group

June 10, 2020

Luz E. Cruz Romero Medicaid Director Puerto Rico Medicaid Program Puerto Rico Department of Health P.O. Box 70184 San Juan, PR 00936-8184

Dear Ms. Romero:

The CMS Division of Pharmacy team has reviewed Puerto Rico's State Plan Amendment (SPA) 20-0001 received in the CMS Division of Program Operations on March 17, 2020. This SPA proposes to allow Puerto Rico to cover MAVYRET, a Hepatitis C drug, through their fee-for-service (FFS) program with the following reimbursement rates:

Independent Pharmacies	AWP -14%	\$2.50 dispensing fee
Hospital and CDT Pharmacies	AWP -15%	\$2.50 dispensing fee
National Chain Pharmacies	AWP -18%	\$1.75 dispensing fee

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 20-0001 is approved with an effective date of March 16, 2020. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Puerto Rico's state plan will be forwarded by the CMS Division of Program Operations.

If you have any questions regarding this amendment, please contact Charlotte Amponsah at (410) 786-1092 or <a href="mailto:charlotte.amponsah@cms.hhs.gov">charlotte.amponsah@cms.hhs.gov</a>.

Sincerely,

/s/

John Coster, PhD, R.Ph., Director Division of Pharmacy

cc: James G. Scott, Division Director, CMS Division of Program Operations Ivelisse Salce, CMS Division of Program Operations - East Branch

	1. TRANSMITTAL NUMBER	2. STATE		
TRANSMITTAL AND NOTICE OF APPROVAL OF	DD 30 0004	DUEDTO DICO		
STATE PLAN MATERIAL	PR-20-0001	PUERTO RICO		
FOR: CENTER FOR MEDICARE & MEDICAID SERVICES (CMS)	3. PROGRAM IDENTIFICATION: Title XIX of the Social Security Act (Medicaid)			
TO: REGIONAL ADMINISTRATOR	PROPOSED EFECTIVE DATE	(iviedicaid)		
Centers for Medicare & Medicaid Services (CMS)	4. PROPOSED ELECTIVE DATE			
Department of Health and Human Services (HHS)	March 16, 2020			
5. TYPE OF PLAN MATERIAL (Check One)	•			
3. THE OFFERN WATERIAL (CHeck One)				
□ NEW STATE PLAN     □ AMENDMENT TO 0	CONSIDERED AS NEW PLAN	MENDMENT AMENDMENT		
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AN	MENDMENT (Separate transmittal for ea-	ch amendment)		
6. FEDERAL STATUTE/REGULATION CITATION	7. FEDERAL BUDGET IMPACT			
Section 1905 (a) of the Social Security Act	a. FFY2020 (3 quarters)	\$ 12,540,945		
42 CFR Part 440	b. FFY <u>2021</u>	\$ 25,721,979		
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8. PAGE NUMBER OF THE PLAN SECTION OR	9. PAGE NUMBER OF THE SUPERS	EDED PLAN SECTION OR		
ATTACHMENT	ATTACHMENT (If Applicable)			
Description for Attachment 3.1-A, pages 4 to 4-a	Description for Attachment 3.1-	Δ nage /		
Description for Attachment 3.1-B, pages 4 to 4-a	Description for Attachment 3.1-			
Attachment 4.19-B, page 1 and page 1a	Attachment 4.19-B, page 1 and p			
10. SUBJECT OF AMENDMENT	Attachment 4.13 B, page 1 and p	Juge 14		
To Provide and Describe Hepatitis C Benefits and Limit	ations			
11. GOVERNOR'S REVIEW (Check One)				
GOVERNOR'S OFFICE REPORTED NO COMMEN	<b>—</b>	CIFIED		
COMMENTS OF GOVERNOR'S OFFICE ENCLOS	ED			
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBI	T			
12. SIGNATURE OF STATE AGENCY OFFICIAL	16. RETURN TO			
13 TVDF NAME	LUZ E. CRUZ-ROMERO			
13. TYPE/NAME	MEDICAID PROGRAM	05.154.51		
LUZ E. CRUZ-ROMERO	PUERTO RICO DEPARTMENT	OF HEALTH		
14. TITLE	PO BOX 70184			
	SAN JUAN PR 00936-8184			
EXECUTIVE DIRECTOR				
15. DATE SUBMITTED				
MAPCH 17, 2020				
MARCH 17, 2020  FOR REGIONAL OFFICE USE ONLY				
17. DATE RECEIVED	18. DATE APPROVED			
MARCH 17, 2020	JUNE 10, 2020			
·	D – ONE COPY ATTACHED			
19. EFECTIVE DATE OF APPROVED MATERIAL	20. SIGNATURE OF REGIONAL OFFIC	CIAL		
MARCH 16, 2020				
21. TYPED NAME	22. TITLE			
JAMES G. SCOTT	DIRECTOR, DIVISION OF PROGE	RAM OPERATIONS		
23. REMARKS				
FORM CMC 170 (07/02)	Lucation of the control of the contr			
FORM CMS-179 (07/92)	Instructions on Back			

STATE/TERRITORY: PUERTO RICO

## AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

## **Description of Limitations**

- Services received outside of the territorial limits of the Commonwealth of Puerto Rico, except ee. for emergency services received in the United States.
- ff. Expenses incurred for the treatment of conditions, resulting from procedures or benefits not covered under this Program. Maintenance prescriptions and required laboratories for the continuity of a stable health condition, as well as any emergencies which could result after the referred procedures, are covered.
- Travel expenses, even when ordered by the primary care physician or participating provider gg. are excluded.
- hh. Eyeglasses, lenses, and hearing aids are excluded, except for beneficiaries under age 21 when it is medically necessary and approved through a prior authorization process.
- ii. Acupuncture services are excluded.
- Rent or purchase of wheelchair or any other vehicle (motor and/or electric) or expenses for jj. the repair or alteration of these vehicles.
- kk. Procedures with the purpose of changing the sex of the beneficiary.
- II. Treatment services for infertility and/or related to conception by artificial means.

## mm. Hepatitis C

Puerto Rico is covering Hepatitis C drugs in the fee-for-service program as outlined in the Puerto Rico provider manual.

TN No.: PR-20-0001 Approval Date: June 10, 2020 Effective Date: March 16, 2020

STATE/TERRITORY: PUERTO RICO

# AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

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- Inpatient hospital services other than those provided in an institution for mental diseases
   Inpatient services are provided within coverage under Health Reform Plan with limitations:
   Limitations on inpatient services:
  - <u>Bed in Semiprivate Room</u>: Coverage will be available twenty-four (24) hours per day, every day of the year.
  - <u>Isolation Room</u>: For medical reasons.
  - <u>Specialized Diagnostic / Treatment</u>: Electrocardiograms, electroencephalograms, arterial gases, and other specialized diagnostic and/or treatment testing that are available in the hospital facilities and which are required to be performed while the patient is hospitalized.

TN No.: PR-20-0001 Approval Date: June 10, 2020 Effective Date: March 16, 2020

STATE/TERRITORY: PUERTO RICO

## AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE MEDICALLY NEEDY

## **Description of Limitations**

- ee. Services received outside of the territorial limits of the Commonwealth of Puerto Rico, except for emergency services received in the United States.
- ff. Expenses incurred for the treatment of conditions, resulting from procedures or benefits not covered under this Program. Maintenance prescriptions and required laboratories for the continuity of a stable health condition, as well as any emergencies which could result after the referred procedures, are covered.
- gg. Travel expenses, even when ordered by the primary care physician or participating provider are excluded.
- hh. Eyeglasses, lenses, and hearing aids are excluded, except for beneficiaries under age 21 when it is medically necessary and approved through a prior authorization process.
- ii. Acupuncture services are excluded.
- jj. Rent or purchase of wheelchair or any other vehicle (motor and/or electric) or expenses for the repair or alteration of these vehicles.
- kk. Procedures with the purpose of changing the sex of the beneficiary.
- II. Treatment services for infertility and/or related to conception by artificial means.

### mm. Hepatitis C

Puerto Rico is covering Hepatitis C drugs in the fee-for-service program as outlined in the Puerto Rico provider manual.

TN No.: PR-20-0001 Approval Date: June 10, 2020 Effective Date: March 16, 2020

STATE/TERRITORY: PUERTO RICO

# AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED **TO THE MEDICALLY NEEDY**

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- 2. Inpatient hospital services other than those provided in an institution for mental diseases Inpatient services are provided within coverage under Health Reform Plan with limitations: Limitations on inpatient services:
  - <u>Bed in Semiprivate Room</u>: Coverage will be available twenty-four (24) hours per day, every day of the year.
  - <u>Isolation Room</u>: For medical reasons.
  - <u>Specialized Diagnostic / Treatment</u>: Electrocardiograms, electroencephalograms, arterial gases, and other specialized diagnostic and/or treatment testing that are available in the hospital facilities and which are required to be performed while the patient is hospitalized.

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STATE/TERRITORY: PUERTO RICO

## METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES FOR EACH OF THE OTHER TYPES OF CARE OR SERVICES

### 1a. Outpatient Hospital Services:

Reasonable cost as specified in federal regulation 250.30(b)(3)(ii).

There is an all-inclusive rate for services provided in governmental medical installations including contract facilities.

#### 1b. Rural Health Clinics:

"Provider clinics" will be reimbursed on the basis of the principles specified in the Medicare regulations located at 42 CFR 405 Part D.

"Non-Provider clinics" will be paid for each ambulatory, other that rural health clinic services, at rates or charges established by the State, subject to the upper limits specific in 42 CFR 447.321. Rural health clinic services will be paid at the Medicare reimbursement rate per visit, as specified in 42 CFR 405.2426 – 405.2429.

## 1c. Federally Qualified Health Care Centers:

These will be reimbursed based upon the principles specified in the Medicare regulations at 42 CFR 405.

### 2. Other Laboratory and X-Rays Services:

Reimbursement on the basis of an all-inclusive out-patient hospital or clinic rates.

### 3. Skilled Nursing Home Services:

Limited to services provided in public facilities.

No FFP presently claimed for these services.

## 4. Physician's Services:

- a. Physicians and other practitioners on salary in clinics and other organized systems. Actual cost included in the clinical fee.
- b. Private practitioners will be paid according to a standard fee regulated by the Secretary of Health.

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# METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES FOR EACH OF THE OTHER TYPES OF CARE OR SERVICES

#### 5. Dental Services:

Limited to services provided in public facilities, including contract facilities. Reimbursement as part of an all-inclusive out-patient hospital or clinic rates.

## 6. Prescribed Drugs and Medical and Supplies:

Reimbursement on the basis of an all-inclusive out-patient hospital or clinic rates.

## **Hepatitis C Covered Drug:**

The reimbursement to the pharmacy providers is based on Average Wholesale Price (AWP) – Discount Fee plus dispensing fee.

Drug Name	GPI Name	Average Wholesale Price (AWP) – Discount Fee		
Mavyret	GLECAPREVIR- PIBRENTASVIR TAB 100-40	Independent Pharmacies	Hospitals and CDT's Pharmacies	National Chains Pharmacies
	MG	14%	15%	18%

Drug Name	GPI Name	Dispensing Fee		
Mavyret	GLECAPREVIR- PIBRENTASVIR TAB 100-40	Independent Pharmacies	Hospitals and CDT's Pharmacies	National Chains Pharmacies
	MG	\$2.50	\$2.50	\$1.75

#### 7. Clinical Services:

Reasonable cost as specified in Federal Regulation 42 CFR 250.30 (B) (3) (ii). There is an all-inclusive rate for services provided in governmental medical installations including contract facilities.

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