

Table of Contents

State/Territory Name: Puerto Rico

State Plan Amendment (SPA)#: PR-23-0006

This file contains the following documents in the order listed

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved SPA Pages

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

Medical Benefits Health Programs Group

December 15, 2023

Dinorah Collazo Ortiz
Puerto Rico's Medicaid Director
Puerto Rico Department of Health
P.O. Box 70184
San Juan, PR 00936-8184

Dear Dinorah Collazo Ortiz,

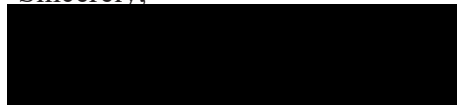
The CMS Division of Pharmacy team has reviewed Puerto Rico's State Plan Amendment (SPA) 23-0006 received in the CMS Medicaid & CHIP Operations Group on March 29, 2023. This SPA proposes to bring Puerto Rico into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

SPA 23-0006 establishes reimbursement for fee-for-service covered outpatient drugs using an actual acquisition cost methodology, with a professional dispensing fee of \$8.96. This SPA also includes reimbursement for fee-for-service 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price. In addition, this SPA also updates the excluded drug listing on the Pharmacy coverage pages.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 23-0006 is approved with an effective date of January 1, 2023. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.


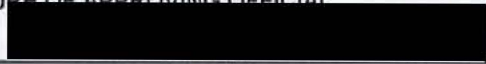
We are attaching a copy of the signed CMS-179 form, as well as the page approved for incorporation into Puerto Rico's state plan. If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov.

Sincerely,



Mickey Morgan
Deputy Director
Division of Pharmacy

cc: Roxanna K. Rosario Serrano, Puerto Rico Department of Health
Milagros Soto, Puerto Rico Department of Health
Ivelisse Salce, Puerto Rico Medicaid State Lead, CMS

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER <u>2 3 — 0 0 0 6</u>	2. STATE <u>PR</u>
	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE <u>January 1, 2023</u>	
5. FEDERAL STATUTE/REGULATION CITATION <u>42 C.F.R. §447</u>	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a FFY <u>2023</u> \$ <u>0</u> b FFY <u>2024</u> \$ <u>0</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Description for Attachment 3.1-A, p. 9, 10, 10a Description for Attachment 3.1-B, p. 9, 10 Attachment 4.19-B, p. 1a	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Description for Attachment 3.1-A, pp. 9, 9a, 10, 10a, 10b Description for Attachment 3.1-B, pp. 9, 9a, 10, 10a, 10b Attachment 4.19-B, p. 1a	
9. SUBJECT OF AMENDMENT Pharmacy reimbursement and coverage to conform to requirements around Puerto Rico joining the federal drug rebate program and other programmatic changes.		
10. GOVERNOR'S REVIEW (Check One) <input type="radio"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="radio"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="radio"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL <input checked="" type="radio"/> OTHER, AS SPECIFIED: Designated to State Medicaid Director		
11. SIGNATURE OF STATE AGENCY OFFICIAL  Dinorah Collazo-Ortiz, Esq., CHC	15. RETURN TO PUERTO RICO MEDICAID PROGRAM PUERTO RICO DEPARTMENT OF HEALTH PO BOX 70184 SAN JUAN PR 00936-8184	
13. TITLE Program Executive Director		
14. DATE SUBMITTED 3/29/2023		
FOR CMS USE ONLY		
16. DATE RECEIVED 3/29/2023	17. DATE APPROVED 12/15/2023	
PLAN APPROVED - ONE COPY ATTACHED		
18. EFFECTIVE DATE OF APPROVED MATERIAL 1/1/2023	19. SIGNATURE OF APPROVING OFFICIAL 	
20. TYPED NAME OF APPROVING OFFICIAL Mickey Morgan	21. TITLE OF APPROVING OFFICIAL Deputy Director, Division of Pharmacy	
22. REMARKS		

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

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

Description of Limitation

11.a. Physical therapy and or chiropractor services as determined medically necessary.

- a. Initial 15 sessions available without prior authorization.
- b. Additional 15 sessions require prior authorization.
- c. The treatment limit is combined with the limit for chiropractic care.
- d. An individual may receive a total of 30 physical therapy and/or chiropractic sessions combined.
- e. Additional sessions beyond 30 are allowed with medical necessity and require a prior authorization process.

12.a. Prescribed drugs

Puerto Rico will provide coverage and reimbursement for covered outpatient drugs consistent with prior authorization and other requirements as set forth under Section 1927 of the Social Security Act.

TN No. 23-0006

Supersedes

TN No. 15-001

Approval Date 12/15/2023 Effective Date: January 1, 2023

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

State Agency Puerto Rico

MEDICAID PROGRAM: REQUIREMENTS RELATING TO COVERED OUTPATIENT
DRUGS FOR THE CATEGORICALLY NEEDY

12.a. Prescribed Drugs: Description of Service Limitation

Citation(s)	Provision(s)
1935 (d)(1)	Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
27(d)(2) and 1935(d)(2)	The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare prescription Drug Benefit Part D.
	<p><input checked="" type="checkbox"/> The following excluded drugs are covered:</p> <p style="padding-left: 40px;">(<i>"All" drugs categories covered under the drug class</i>) (<i>"Some" drugs categories covered under the drug class</i> -<i>List the covered drug categories not individual drug products directly under the appropriate drug class</i>) (<i>"None" of the drugs under this drug class are covered</i>)</p> <p><input checked="" type="checkbox"/> (a) agents when used for anorexia, weight loss, weight gain are excluded as a general rule. Puerto Rico provides coverage of medically-necessary mental health drugs when used in the treatment of anorexia according to the medical psychiatric practice accepted norms as required for the diagnosis, prevention, and treatment of the mental health disease.</p> <p><input type="checkbox"/> (b) agents when used to promote fertility</p> <p><input type="checkbox"/> (c) agents when used for the symptomatic relief of cough and colds</p> <p><input checked="" type="checkbox"/> (d) prescription vitamins and mineral products are excluded as a general rule, except prenatal vitamins and fluoride. Puerto Rico also covers some vitamins and mineral products when there are prescribed and are medically necessary.</p>

TN No. 23-0006

Supersedes

TN No. 13-002

Approval Date 12/15/2023 Effective Date: January 1, 2023

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State Agency Puerto Rico
AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND
SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

12.a. Prescribed Drugs: Description of Service Limitation

(e) selective non-legend outpatient drugs for all eligible beneficiaries.

(f) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee (see specific drug categories below)

TN No. 23-0006
Supersedes
TN No. 13-002

Approval Date 12/15/2023 Effective Date: January 1, 2023 _____

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

Description of Limitation

11 .a. Physical therapy and or chiropractor services as determined medically necessary.

The services provided to medically needy beneficiaries are the same as those provided to categorically needy beneficiaries.

12.a. Prescribed drugs

The services provided to medically needy beneficiaries are the same as those provided to categorically needy beneficiaries.

TN No. 23-0006

Supersedes

TN No. 15-001

Approval Date 12/15/2023 Effective Date: January 1, 2023

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

State Agency Puerto Rico

MEDICAID PROGRAM: REQUIREMENTS RELATING TO COVERED OUTPATIENT
DRUGS FOR THE CATEGORICALLY NEEDY

12.a. Prescribed Drugs: Description of Service Limitation

LEFT BLANK INTENTIONALLY

TN No. 23-0006

Supersedes

TN No. 13-002

Approval Date 12/15/2023 Effective Date: January 1, 2023

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
 STATE/TERRITORY: PUERTO RICO
 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:

The professional dispensing fee for all fee-for-service drugs is \$8.96.

Unless otherwise specified, payment for fee-for-service drugs, to include specialty and clotting factor drugs, is the lowest of:

1. the actual acquisition costs of the drugs, defined as the National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee;
2. the state-established maximum allowable cost (MAC), plus a professional dispensing fee;
- or
3. the provider's usual and customary charge to the general public.

Puerto Rico Medicaid will calculate the actual acquisition cost of multiple source drugs in conformity with the upper payment limits established under 42 C.F.R. §447.512.

For 340B purchased fee-for-service drugs prescribed by an authorized prescriber, the maximum allowed to be billed is as follows:

- o A covered entity described in section 1927(a)(5)(B) of the Act. (340B covered entity pharmacy) can bill no more than their actual acquisition cost plus the professional dispensing fee.
- o A contracting pharmacy under contract with a 340B covered entity described in section 1927(a)(5)(B) of the Act can bill no more than their actual acquisition cost plus a professional dispensing fee.

Fee-for-service drugs purchased through the Federal Supply Schedule and fee-for-service drugs purchased at nominal price (outside of the 340B program) are reimbursed at actual acquisition cost plus the professional dispensing fee.

Puerto Rico Medicaid does not cover the distribution of drugs through mail order or long-term care facilities.

Provider administered drugs (PADs) in all settings will be reimbursed using the current MAC rate. PADs will be reimbursed using the Medicare fee schedule if no MAC is available. There is no professional dispensing fee.

For provider-administered drugs purchased through the Federal Public Health Service's 340B Drug Pricing program, reimbursement shall be the 340B actual acquisition cost.

Investigational drugs are not a covered service,

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.