Table of Contents

State/Territory Name: New York

State Plan Amendment (SPA)#: 24-0073

This file contains the following documents in the order listed below:

- 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



Medicaid Benefits and Health Programs Group

November 20, 2024

Amir Bassiri New York State Department of Health Division of Finance and Rate Setting 99 Washington Ave- One Commerce Plaza Suite 1432 Albany, NY 12210

Dear Director Bassiri,

We have reviewed New York's State Plan Amendment (SPA) 24-0073 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on September 18, 2024. This SPA amends the State Plan for coverage of drugs authorized for import by the Food and Drug Administration when medically necessary during drug shortages.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that NY-24-0073 is approved with an effective date of August 1, 2024.

We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into New York's state plan. If you have any questions regarding this amendment, please contact Whitney Swears at 410-786-6543 or via email at Whitney.Swears@cms.hhs.gov.

Sincerely,

Cynthia R. Denemark Director Division of Pharmacy

cc: Regina Deyette, New York State Department of Health Kimberly Leonard, New York State Department of Health Michelle Levesque, New York State Department of Health Bonny DeCastro, New York State Department of Health Melvina Harrison, CMS, Medicaid and CHIP Operations Group

| TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES | 1. TRANSMITTAL NUMBER 2. STATE 2. 4 — 0 0 7 3 N Y 3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT XIX XXI | | | | |
|---|---|--|--|--|--|
| TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES | 4. PROPOSED EFFECTIVE DATE August 1, 2024 | | | | |
| 5. FEDERAL STATUTE/REGULATION CITATION | 6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a FFY 08/01/24-09/30/24 \$ 0 b. FFY 10/01/24-09/30/25 \$ 0 | | | | |
| § 1905(a)(12) Prescribed Drugs, Dentures, Prosthetic Devices; and Eyeglasses | | | | | |
| 7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT | 8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) | | | | |
| Attachment 3.1-A Supplement: Page 2(c.1) Attachment 3.1-B Supplement: Page 2(c.1) | Attachment 3.1-A Supplement: Page 2(c.1) Attachment 3.1-B Supplement: Page 2(c.1) | | | | |
| 9. SUBJECT OF AMENDMENT | - 2 | | | | |
| Coverage of Prescribed Drugs in Cases of a Drug Shortage | | | | | |
| 10. GOVERNOR'S REVIEW (Check One) GOVERNOR'S OFFICE REPORTED NO COMMENT COMMENTS OF GOVERNOR'S OFFICE ENCLOSED NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL | OTHER, AS SPECIFIED: | | | | |
| | 15. RETURN TO | | | | |
| | New York State Department of Health | | | | |
| 12. TYPED NAME | Division of Finance and Rate Setting 9 Washington Ave – One Commerce Plaza | | | | |
| THE TITLE | Suite 1432 | | | | |
| Medicaid Director | Albany, NY 12210 | | | | |
| 14. DATE SUBMITTED September 18, 2024 | | | | | |
| FOR CMS USE ONLY | | | | | |
| 16. DATE RECEIVED September 18, 2024 | 7. DATE APPROVED November 20, 2024 | | | | |
| PLAN APPROVED - ON | | | | | |
| | 9 SIGNATURE OF ARRIGNAUMONOFFICIAL | | | | |
| August 1, 2024 | | | | | |
| 20. TYPED NAME OF APPROVING OFFICIAL | 1. TITLE OF APPROVING OFFICIAL | | | | |
| Cynthia R. Denemark | Director, Division of Pharmacy | | | | |
| 22. REMARKS | | | | | |

New York 2(c.1)

1905(a)(12) Prescribed Drugs, Dentures, and Prosthetic Devices; and Eyeglasses

8. The State will cover APIs that are included in extemporaneously compounded prescriptions when the API serves as the active drug component in the compounded formulation. A current list of covered APIs can be found at the following at:

https://www.emedny.org/info/formfile.aspx

9. Drug Shortages: Prescribed drugs that are not covered outpatient drugs (including drugs authorized for import by the Food and Drug Administration) are covered when medically necessary during drug shortages identified by the Food and Drug Administration.

13c. Preventive Services

New York State Medicaid covers and reimburses all United States Preventive Services Task Force (USPSTF) grade A and B preventive services and approved vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), and their administration, without cost-sharing, when provided in a practitioner's office.

Preventive Services specified in section 4106 of the Affordable Care Act are all available under the State Plan and are covered under the physician, other practitioner, nurse-midwife and nurse practitioner service benefits and are reimbursed according to the methodologies provided in Attachment 4.19-B.

The State will maintain documentation supporting expenditures claimed for these Preventive Services and ensure that coverage and billing codes comply with any changes made to the USPSTF or ACIP recommendations.

Lactation Consultant Services

Effective April 1, 2021, evidence-based breastfeeding education and lactation counseling consistent with the United States Preventive Services Task Force (USPSTF) recommendation will be covered as a preventive service to prevent adverse outcomes and promote health of infants. Qualified providers include licensed physicians, licensed physician assistants, licensed pediatric or family nurse practitioners, licensed midwives, and licensed registered nurses. All practitioners must be certified as lactation educators/counselors by a nationally recognized accrediting agency.

Breastfeeding education and lactation counseling services must be recommended by a physician or other licensed practitioner of the healing arts acting within his or her scope of practice under state law.

| TN <u>#24-00</u> | 073 | Approval Date | November 20, 2024 |
|------------------|----------|----------------|-------------------|
| Supersedes TN | #21-0014 | Effective Date | August 1, 2024 |

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