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State/Territory Name: California

State Plan Amendment (SPA)#: 24-0030

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

October 9, 2024

Tyler Sadwith, State Medicaid Director
Department of Health Care Services
Attn: Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Director Sadwith:

We have reviewed California's State Plan Amendment (SPA) 24-0030 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on August 26, 2024. This SPA proposes to amend the State Plan to authorize 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 CA-24-0030 is approved with an effective date of July 1, 2024.

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

Sincerely,

Cynthia R.
Denemark -S

Digitally signed by
Cynthia R. Denemark -S
Date: 2024.10.09
15:10:59 -04'00'

Cynthia R. Denemark
Director
Division of Pharmacy

cc: Lindy Harrington, Assistant SMD, Department of Health Care Services
Rene Mollow, Director of Benefits and Coverage, Department of Health Care Services
Lisa Ghotbi, Chief of Pharmacy Benefits, Department of Health Care Services
Angeli Lee, SPA Coordinator, Department of Health Care Services
Cheryl Young, 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 4 — 0 0 3 0

2. STATE

CA

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

July 1, 2024

5. FEDERAL STATUTE/REGULATION CITATION

42 CFR §440.120

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 24-25 \$ 0
b. FFY 25-26 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Limitations to Attachment 3.1-A, page 17
Limitations to Attachment 3.1-B, page 17

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Limitations to Attachment 3.1-A, page 17
Limitations to Attachment 3.1-B, page 17

9. SUBJECT OF AMENDMENT

To specify that 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.

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:

Please note: The Governor's Office does not wish to review the State Plan Amendment.

11. SIGNATURE OF STATE AGENCY OFFICIAL

TYPED NAME
Tyler Sadwith

13. TITLE
State Medicaid Director

14. DATE SUBMITTED
August 26, 2024

15. RETURN TO

Department of Health Care Services
Attn: Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

FOR CMS USE ONLY

16. DATE RECEIVED
August 26, 2024

17. DATE APPROVED
October 9, 2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
July 1, 2024

19. SIGNATURE OF APPROVING OFFICIAL
Cynthia R. Denemark -S
Digitally signed by Cynthia R. Denemark -S
Date: 2024.10.09 18:11:17 -0400

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia Denemark

21. TITLE OF APPROVING OFFICIAL
Director, Division of Pharmacy

22. REMARKS

TYPE OF SERVICE	PROGRAM COVERAGE**	PRIOR AUTHORIZATION OR OTHER REQUIREMENTS*
12 Pharmaceutical services and prescribed drugs	<p>Covered when prescribed by a licensed practitioner.</p> <p>Drugs for the treatment of hospital inpatients are covered as encompassed in the formulary of the hospital.</p> <p>Drugs administered for chronic outpatient hemodialysis in renal dialysis centers and community hemodialysis units are covered, but payable only when included in the all-inclusive rate.</p> <p>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.</p>	<p>Prior authorization is not required for drugs listed on the Contract Drug List (CDL), except that certain drugs on the CDL are subject to prior authorization unless used as specified therein.</p> <p>Except for hospital inpatients, prescriptions shall not exceed a 100-calendar-day supply.</p> <p>Hospital inpatient drugs, as encompassed in the formulary of the hospital, do not require prior authorization.</p> <p>Hospital discharge medications may not exceed a ten-day supply.</p> <p>Certain drugs on the CDL are subject to minimum or maximum dispensing quantities.</p> <p>Drugs not on the CDL are subject to prior authorization, except that certain drugs are excluded from Medi-Cal program coverage.</p>

*Prior authorization is not required for emergency service.

**Coverage is limited to medically necessary services.

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TN No. 24-0030
Supersedes
TN No. 20-0039

Approval Date: October 9, 2024

Effective Date: July 1, 2024