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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 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 TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES 5. FEDERAL STATUTE/REGULATION CITATION 42 CFR §440.120 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	2 4 — 0 0 3 0 CA		
SUBJECT OF AMENDMENT To specify that prescribed drugs that are not covered outpatient of the specific	drugs (including drugs authorized for import by the Food and		
Drug Administration) are covered when medically necessary durin Administration.			
10. GOVERNOR'S REVIEW (Check One)			
O GOVERNOR'S OFFICE REPORTED NO COMMENT	OTHER, AS SPECIFIED:		
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	Please note: The Governor's Office does not wish to review		
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	the State Plan Amendment.		
11. SIGNATURE OF STATE AGENCY OFFICIAL	15. RETURN TO		
	Department of Health Care Services		
12/TYPED NAME	Attn: Director's Office		
Tyler Sadwith	P.O. Box 997413, MS 0000 Sacramento, CA 95899-7413		
ate Medicaid Director			
14. DATE SUBMITTED August 26, 2024			
FOR CMS USE ONLY			
16. DATE RECEIVED August 26, 2024	17. DATE APPROVED October 9, 2024		
PLAN APPROVED - O			
18. EFFECTIVE DATE OF APPROVED MATERIAL July 1, 2024	19. L		
20. TYPED NAME OF APPROVING OFFICIAL	21. TITLE OF APPROVING OFFICIAL		
Cynthia Denemark	Director, Division of Pharmacy		
22. REMARKS			

(This chart is an overview only.) STATE PLAN CHART Limitations on Attachment 3.1-A Page 17

Effective Date: July 1, 2024

TYPE OF SERVICE	PROGRAM COVERAGE**	PRIOR AUTHORIZATION OR OTHER REQUIREMENTS*
Pharmaceutical services and prescribed drugs	Covered when prescribed by a licensed practitioner.	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.
	Drugs for the treatment of hospital inpatients are covered as encompassed in the formulary of the hospital.	Except for hospital inpatients, prescriptions shall not exceed a 100-calendar-day supply.
	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.	Hospital inpatient drugs, as encompassed in the formulary of the hospital, do not require prior authorization.
		Hospital discharge medications may not exceed a ten-day supply.
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.	are not covered outpatient drugs (including drugs authorized for import by	Certain drugs on the CDL are subject to minimum or maximum dispensing quantities.
	Drugs not on the CDL are subject to prior authorization, except that certain drugs are excluded from Medi-Cal program coverage.	
	Pharmaceutical services and	Pharmaceutical services and prescribed drugs Covered when prescribed by a licensed practitioner. Drugs for the treatment of hospital inpatients are covered as encompassed in the formulary of the hospital. 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. 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

TN No. <u>24-0030</u> Supersedes TN No. <u>20-0039</u>

Approval Date: October 9, 2024

^{*}Prior authorization is not required for emergency service. **Coverage is limited to medically necessary services.

(This chart is an overview only.) STATE PLAN CHART Limitations on Attachment 3.1-B Page 17

	TYPEOFSERVICE	PROGRAM COVERAGE**	PRIOR AUTHORIZATION OR OTHER REQUIREMENTS*
	Pharmaceutical services and prescribed drugs	Covered when prescribed by a licensed practitioner.	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.
		Drugs for the treatment of hospital inpatients are covered as encompassed in the formulary of the hospital.	Except for hospital inpatients, prescriptions shall not exceed a 100-calendar-day supply.
		Drugs administered for chronic outpatient hemodialysis in renal dialysis centers and community hemodialysis units are	Hospital inpatient drugs, as encompassed in the formulary of the hospital, do not require pricauthorization.
		covered, but payable only when included in the all-inclusive rate.	Hospital discharge medications may not exceed a ten-day supply.
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		Drugs not on the CDL are subject to prior authorization, except that certain drugs are excluded from Medi-Cal program coverage.	

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Effective Date: July 1, 2024 October 9, 2024 Approval Date:

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