

September 27, 2024

Brian Zolynas
Division of Medicaid and Children's Health Operations
U.S. Department of Health & Human Services
Centers for Medicare & Medicaid Services
90 Seventh Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

RE: Arizona SPA # AZ-24-0013, Prescribed Drug SPA

Dear Mr. Zolynas:

Enclosed is State Plan Amendment (SPA) # AZ-24-0013, Prescribed Drug SPA. This SPA authorizes coverage of certain drugs when the FDA allows temporary importation of non-FDA approved drugs to mitigate the effects of a drug shortage, effective July 1, 2024.

Tribal Consultation on this SPA occurred on August 5, 2024. The Tribal Consultation presentation is available on the following webpage:

<https://www.azahcccs.gov/AmericanIndians/TribalConsultation/>

Public Notice for this SPA was posted on the following webpages:

<https://www.azahcccs.gov/AHCCCS/Downloads/PublicNotices/AZ-SPAPublicNotice-PrescribedDrugShortage.pdf>

If there are any questions about the enclosed SPA, please contact Maxwell Seifer at Maxwell.Seifer@azahcccs.gov or 602-417-4722.

Sincerely,



Kyle Sawyer
Assistant Director, Public Policy and Strategic Planning
Arizona Health Care Cost Containment System (AHCCCS)

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER 24 — 0013	2. STATE AZ
3. PROGRAM IDENTIFICATION: TITLE 19 OF THE SOCIAL SECURITY ACT	

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 Part 447.201

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY: **2025** \$ **0**
b. FFY: **2026** \$ **0**

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1-A Limitations Page 9

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Attachment 3.1-A Limitations Page 9

9. SUBJECT OF AMENDMENT
This SPA authorizes coverage of certain drugs when the FDA allows temporary importation of non-FDA approved drugs to mitigate the effects of a drug shortage, effective July 1, 2024.

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:

11. SIGNATURE OF STATE AGENCY OFFICIAL



15. RETURN TO
Kyle Sawyer
801 E. Jefferson St., MD #4200
Phoenix, AZ 85034

12. TYPED NAME
Kyle Sawyer

13. TITLE
Assistant Director, Public Policy and Strategic Planning

14. DATE SUBMITTED: September 27, 2024

FOR CMS USE ONLY

16. DATE RECEIVED

17. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL

21. TITLE OF APPROVING OFFICIAL

22. REMARKS

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12a. Prescribed drugs.

Medicare Part D drugs are not covered for full benefit dual eligible members, as coverage is provided through Medicare Part D PDPs and MAPDs

Prescription drugs for covered transplantation services shall be provided in accordance with AHCCCS transplantation policies.

AHCCCS only covers over-the-counter medications in place of a covered prescription medication that is clinically appropriate, equally safe and effective, and less costly than the covered prescription medication.

In compliance with Section 1927(b) of the Social Security Act (the Act), the State collects drug rebates in accordance with established policy for drug rebate agreements as provided in Exhibit 12(a) to Attachment 3.1-A.

CMS has authorized the state of Arizona to enter into Outcomes-Based contract arrangements with drug manufacturers for drugs provided to Medicaid beneficiaries. These contracts will be executed on the contract template titled “Outcomes-Based Supplemental Rebate Agreement” submitted to CMS and authorized for use beginning July 1, 2019.

[AHCCCS covers select prescribed drugs when medically necessary. Prescribed drugs that are not covered outpatient drugs \(including drugs authorized for import by the Food and Drug Administration\) are also covered when medically necessary during drug shortages identified by the Food and Drug Administration.](#)

12c. Prosthetic devices.

Prosthetic devices are limited to devices prescribed by a physician or other licensed practitioner to artificially replace missing, deformed or malfunctioning portions of the body and which are medically necessary to the rehabilitation of the member.

Covered prosthetic devices for members age 21 and older do not include hearing aids, cochlear implants, bone anchored hearing aids, percussive vests, microprocessors for controlled joints for the lower limbs in addition to microprocessor-controlled joints for the lower limbs, penile implants, and vacuum devices.

Orthotic devices, which are defined as devices that are prescribed by a physician or other licensed practitioner of the healing arts to support a weak or deformed portion of the body, are covered when the use of the orthotic is medically necessary as the preferred treatment option consistent with Medicare guidelines and the orthotic is less expensive than all other treatment options or surgical procedures to treat the same diagnosed condition.

12d. Eyeglasses.

Eye examinations for prescriptive lenses and the provision of prescriptive lenses under EPSDT services.

Adult services are limited to eyeglasses and contact lenses as the sole prosthetic device after a cataract extraction.

13. Other diagnostic, screening, preventive, and rehabilitative services, i.e., other than those provided elsewhere in the plan.

13a. Diagnostic Services.

Genetic testing is not covered unless the results of the genetic tests are necessary to differentiate between treatment options. Genetic testing is not covered to determine specific diagnoses or syndromes when such determination would not definitively alter the medical treatment of the member.

Supersedes [TN No. 19-004](#)
~~July 1, 2024~~
[TN No. 15-003](#)

—Approval Date: _____

—Effective Date: