

Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

November 5, 2021

Ms. Kim Bimestefer Executive Director Colorado Department of Health Care Policy & Financing 1570 Grant Street Denver, Colorado 80203

Dear Ms. Bimestefer:

The CMS Division of Pharmacy team has reviewed Colorado's State Plan Amendment (SPA) 21-0017 received in the CMS Medicaid & CHIP Operations Group on August 13, 2021. This SPA proposes to update the outpatient pharmacy rate methodology for blood clotting factor drugs by incorporating Average Acquisition Cost (AAC) and Clotting Factor Maximum Allowable Cost (CFMAC) rates, along with a \$0.03/unit enhanced professional dispensing fee.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 21-0017 is approved with an effective date of April 1, 2022. We are attaching a copy of the revised, signed CMS-179 form, as well as the page approved for incorporation into Colorado's state plan.

If you have any questions regarding this amendment, please contact Lisa Shochet at (410) 786-5445 or <u>lisa.shochet@cms.hhs.gov</u>.

Sincerely,



John M. Coster, Ph.D., R.Ph. Director Division of Pharmacy

cc: Dr. Tracy Johnson, Colorado Department of Health Care Policy & Financing Laurel Karabatsos, Colorado Department of Health Care Policy & Financing Bettina Schneider, Colorado Department of Health Care Policy & Financing Russell Ziegler, Colorado Department of Health Care Policy & Financing Jami Gazarro, Colorado Department of Health Care Policy & Financing Amy Winterfeld, Colorado Department of Health Care Policy & Financing Curtis Volesky, CMS, Medicaid & CHIP Operations Group

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES		FORM APPROVED OMB NO. 0938-0193
TRANSMITTAL AND NOTICE OF APPROVAL OF	1. TRANSMITTAL NUMBER: 21–0017	2. STATE: COLORADO
STATE PLAN MATERIAL	3. PROGRAM IDENTIFICATION:	
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE: April 1, 2022	
5. TYPE OF PLAN MATERIAL (Check One):		
NEW STATE PLAN AMENDMENT TO BE CONSIDERED	AS A NEW PLAN X AMEN	DMENT
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AM	ENDMENT (Separate transmittal for each a	amendment)
6. FEDERAL STATUTE/REGULATION CITATION:	7. FEDERAL BUDGET IMPACT:	
42 CFR 440.120	a. FFY 2022: (\$1,413,998) b. FFY 2023: (\$2,827,996)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Attachment 4.19-B – Methods and Standards for Establishing Payment Rates – 12.a. – Pharmaceutical Services – Pages 1-3 of 3 (TN 20-0013, 21-0008) 	
Attachment 4.19-B – Methods and Standards for Establishing Payment Rates – 12.a. – Pharmaceutical Services – Pages 1-2 of 3 Pages 1-3 of 3		
10. SUBJECT OF AMENDMENT: Updates the outpatient pharmacy rate methodology for blood clotting for Clotting Factor Maximum Allowable Cost (CFMAC) rates	actor drugs by incorporating Average A	cquisition Cost (AAC) and
11. GOVERNOR'S REVIEW (Check One):		
GOVERNOR'S OFFICE REPORTED NO COMMENT X OT	HER, AS SPECIFIED	
	vernor's letter dated 14 July, 2021	
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	vernor s letter dated 14 outy, 2021	
12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: Colorado Department of Health Care Policy and Financin 1570 Grant Street Denver, CO 80203-1818	
13. TYPED NAME:		
Tracy Johnson		
14. TITLE:	Attn: Amy Winterfeld	
Medicaid Director		
	-	
15. DATE SUBMITTED: August 13, 2021		
FOR REGIONAL	DFFICE USE ONLY	
17. DATE RECEIVED	18. DATE APPROVED	
August 13, 2021	November 5, 2021	
PLAN APPROVED – (ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL April 1, 2022	20. SIGNATURE OF REGIONAL OFFIC	
21. TYPED NAME	22. TITLE	
John M. Coster, Ph.D., R.Ph.	Director, Division of Pharmacy	
23. REMARKS 8/25/2021 - Pen and Ink change authorized by state for Box 8 to	o read "Pages 1-3 of 3".	

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM

STATE OF COLORADO

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES-OTHER TYPES OF CARE

12.a. Pharmaceutical Services:

- A. Reimbursement for covered outpatient drugs dispensed by retail community pharmacies, rural pharmacies, mail order pharmacies, specialty pharmacies, government pharmacies, institutional and long-term care pharmacies, shall be based upon the lower of:
 - 1. The usual and customary charge to the public; or
 - 2. The allowed ingredient cost as defined in B plus a professional dispensing fee.
- B. The allowed ingredient cost shall be the lesser of Colorado Actual AcquisitionCost (AAC) as defined in F, National Average Drug Acquisition Cost (NADAC)or submitted ingredient cost. If AAC and NADAC are not available, the allowed ingredient cost shall be the lesser of Maximum Allowable Cost (MAC) or submitted ingredient cost.
- C. Reimbursement for clotting factor drugs dispensed by specialty pharmacies, Hemophilia Treatment Centers, or any other pharmacy provider, shall be based upon the lower of:
 - 1. The usual and customary charge to the general public; or
 - 2. The allowed ingredient cost as defined in D plus a professional dispensing fee.
- D. The allowed ingredient cost for clotting factor drugs shall be the lesser of the Colorado Average Acquisition Cost (AAC) as defined in E or submitted ingredient cost. If AAC is not available, the allowed ingredient cost shall be the lesser of the Clotting Factor Maximum Allowable Cost (CFMAC) or submitted ingredient cost.
- E. AAC for clotting factor drugs is the established allowable reimbursement rate using the actual acquisition cost rates specific to each clotting factor drug.

The Department shall update the AAC rate on a regular basis based on changes in the pharmacies' acquisition costs. Clotting factor drugs that are reimbursed at AAC or submitted ingredient cost shall receive an enhanced per unit professional dispensing fee as defined in R, in addition to the usual professional dispensing fee as defined in Q.

F. AAC is the established maximum allowable reimbursement rate for covered drugs using the actual acquisition cost for like drugs grouped by Generic Code Number (GCN) or Generic Sequence Number(GSN).

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM

STATE OF COLORADO

Attachment 4.19-B Page 2 of 3

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES-OTHER TYPES OF CARE

- G. The Department shall update AAC on a regular basis based on changes in pharmacies' acquisition costs and national pricing benchmarks such as WAC. The AAC price list is available through the Department's website (colorado.gov/hcpf).Drugs acquired through the Federal Supply Schedule (FSS) shall be reimbursed at their actual acquisition cost, plus a professional dispensing fee.
- H. Drugs acquired at Nominal Price (as defined in 42 CFR §447.502) outside of FSS or the 340B Pricing Program shall be reimbursed at their actual acquisition cost plus a professional dispensing fee.
- I. Drugs dispensed by Indian Health Service/Tribal pharmacies shall be reimbursed at an encounter rate.
- J. Drugs dispensed by 340B Covered Entities purchasing drugs through the 340B Pricing Program will be reimbursed at their actual acquisition cost, plus a professional dispensing fee.
- K. Drugs dispensed by Covered Entities (as defined in the Social Security Act, Section 1927(a)(5)(B)) not purchased through the 340B Pricing Program shall be reimbursed as defined in A.
- L. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.
- M. Physician-administered drugs are reimbursed at the published Medicare Average Sales Price (ASP) Drug Pricing File minus 3.3 percent for drugs included in that file. Physician administered drugs that are not included in the Medicare ASP Drug Pricing File will be reimbursed at Wholesale Acquisition Cost (WAC). Covered entities using drugs purchased at the prices authorized under Section 340B of the Public Health Services Act for Medicaid members must bill Medicaid the 340B purchase price. No professional dispensing fee is applied.
 - Effective November 26, 2019, injectable opioid antagonists are reimbursed at the published Medicare ASP Drug Pricing File plus 2.2%.
- N. Experimental or investigational drugs will not be allowed for reimbursement.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT MEDICAL ASSISTANCE PROGRAM

STATE OF COLORADO

Attachment 4.19-B Page 3 of 3

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES-OTHER TYPES OF CARE

- O. Any pharmacy, except a mail order pharmacy, that is the only pharmacy enrolled with the Medical Assistance Program within a twenty-mile radius, may submit a written request to the Department requesting the designation of a rural pharmacy.
- P. In the aggregate, the Medical Assistance Program expenditures for outpatient drugs shall be in compliance with the federal upper limits as set forth in 42 CFR §§447.512 and 447.514.
- Q. Professional dispensing fees shall be established based upon reported dispensing costs provided through the Medical Assistance Program's Cost of Dispensing (COD) survey. The professional dispensing fees for all pharmacies except government and rural pharmacies shall be tiered based upon annual total prescription volume. The professional dispensing fees shall be tiered at:
 - Less than 60,000 total prescriptions filled per year = \$13.40
 - Between 60,000 and 90,000 total prescriptions filled per year = \$11.49
 - Between 90,000 and 110,000 total prescriptions filled per year = \$10.25
 - Greater than 110,000 total prescriptions filled per year = \$9.31

The determination of total prescription volume shall be completed by surveying pharmacies on an annual basis. Pharmacies failing to respond to the survey shall be reimbursed the \$9.31 professional dispensing fee.

The tiered professional dispensing fee shall not apply to government pharmacies which shall instead be reimbursed a \$0.00 professional dispensing fee.

The tiered professional dispensing fee shall not apply to rural pharmacies, as defined in O, which shall instead be reimbursed a \$14.14 professional dispensing fee.

R. The enhanced professional dispensing fee for clotting factor drugs shall be \$0.03 per unit.