

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

PROPOSED

PUBLIC NOTICE

Cellular and Gene Therapy

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the **Delaware Code**) and under the authority of 31 **Del.C.** §512, Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DHSS/DMMA) is proposing to amend Title XIX Medicaid State Plan Attachment 4.19-B pages 14 and 14a, specifically, to change pricing logic for clotting factors and specialty medications to control cost.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs, or other written materials concerning the proposed new regulations must submit same to, Planning and Policy Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906, by email to DHSS_DMMA_Publiccomment@Delaware.gov, or by fax to 302-255-4413 by 4:30 p.m. on December 2, 2024. Please identify in the subject line: Cellular and Gene Therapy

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend Title XIX Medicaid State Plan regarding Cellular and Gene Therapy.

Statutory Authority

- Executive Order 14087
- CMS Rule 2434-F

Background

The CGT Access Model was developed by the Centers for Medicare and Medicaid Services (CMS) in response to President Biden's Executive Order 14087 and aims to improve the lives of people with Medicaid living with rare and severe diseases by increasing access to potentially transformative treatments. Cellular and gene therapies are a rapidly growing class of one-time treatments, many of which are developed to treat rare and severe diseases, such as sickle cell disease. They can correct underlying causes of a disease, address symptoms, and halt disease progression. However, the high cost of these treatments makes it difficult for state Medicaid agencies to pay for them. Initially, the model will focus on access to gene therapy treatments for people living with sickle cell disease, a genetic blood disorder that disproportionately affects African Americans. This will change pricing logic for clotting factors and specialty medications to control cost in these 2 high price drug categories.

Summary of Proposal

Purpose

The purpose of this proposed regulation is to update the definition of an outpatient drug and participate in the CGT Access model with CMS.

Summary of Proposed Changes

Effective July 1, 2025, the DHSS/DMMA proposes to amend Title XIX Medicaid State Plan to change pricing logic for clotting factors and specialty medications to control cost.

Public Notice

In accordance with the *federal* public notice requirements established in Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 440.386 and the *state* public notice requirements of Title 29, Chapter 101 of the **Delaware Code**, DHSS/DMMA gives public notice and provides an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments must be received by 4:30 p.m. on December 2, 2024.

Centers for Medicare and Medicaid Services Review and Approval

The provisions of this state plan amendment (SPA) are subject to approval by the Centers for Medicare and Medicaid Services (CMS). The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Provider Manuals and Communications Update

Also, there may be additional provider manuals that may require updates as a result of these changes. The applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals and/or Delaware Medical Assistance Portal will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and provide other pertinent information regarding DMAP updates. DMAP updates are available on the Delaware Medical Assistance Portal website: <https://medicaid.dhss.delaware.gov/provider>

Fiscal Impact

There is no anticipated fiscal impact.

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE/TERRITORY: **DELAWARE**

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

Overview

The Delaware Medical Assistance Program (DMAP) will reimburse pharmaceuticals using the lower of:

• ~~The usual and customary (U & C) charge to the general public for the product,~~

1. All prescribed drugs, devices, and supplies, including DMAP covered non-legend and legend products that are prescribed by an authorized prescriber, DMAP will reimburse using the following hierarchy methodology. National Average Drug Acquisition Cost (NADAC); if no NADAC,

~~National Average Drug Acquisition Cost (NADAC);~~

2. Delaware Maximum Allowable Cost (DMAC); (DMAC). (Delaware Medicaid and Medical Assistance MAC) includes all types of medication, including specialty and hemophilia products). If no NADAC or DMAC,

~~Actual Acquisition Cost (AAC);~~

3. Wholesale Acquisition Cost (WAC),

- WAC for legend
- WAC minus 2% for non-legend

4. The usual and customary charge submitted by the provider if it is lower.

5. Federal Supply Schedule purchased drugs will be reimbursed at the provider's actual acquisition cost.

6. Drugs acquired at Nominal Price (outside of 340B or Fee for Service) will be reimbursed at the provider's acquisition cost.

7. Long-term care pharmacy providers supplying covered drugs to participants in long-term care facilities shall be reimbursed as outlined in items 1-6 above in this section.

8. Drugs not distributed by a retail community pharmacy and distributed primarily through a Specialty Pharmacy, or the mail (such as specialty drugs) will be reimbursed as outlined in items 1-6 above in this section. DMAC is market based and includes all drug types.

9. Clotting factors from Specialty Pharmacy, Hemophilia Treatment Centers (HTC) will be reimbursed as outlined in items 1-6 in this section. DMAC is market based and includes all types of drugs.

10. Physician Administered Drugs (PAD) will be reimbursed as outlined in items 1-6 above in this section. DMAC is market based and includes all types of drugs.

11. Investigational Drugs that are prior authorized by DMAP will be reimbursed at AAC.

Medications listed on the High Investment Medication list are carved out of managed care and paid for by DMAP. All other services provided for the patient are the responsibility of the MCO. The High Investment Medication list is available on the DMMA pharmacy portal as www.medicaid.dhss.Delaware.gov.

Delaware will pay for High Investment list medications by using the lesser of methodology:

- 1) Actual Acquisition Cost
- 2) Wholesale Acquisition Cost (WAC)
- 3) ASP + 6 % if available
- 4) Billed Charges

DMAP will meet the reimbursement of FUL defined drugs in the aggregate by reviewing that the NADAC does not exceed the FUL levels.

Methodology for establishing AAC is provided in the table on page Attachment 4.19-B Page 14a.

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Entities that purchase Section 340B of the Public Health Service Act products must request to use these drugs for all DMAP patients, including Medicaid fee-for-service patients and for patients whose care is covered by Medicaid Managed Care Organizations.

Professional Dispensing Fee

There is one-time professional fee per thirty (30)-day period unless the class of drugs is routinely prescribed for a limited number of days.

Definitions

Delaware Maximum Allowable Cost (DMAC) - a maximum price set for reimbursement:

- When a single source product has Average Selling Prices provided by the manufacturer that indicates the WAC is exaggerated,
- When the NADAC does not reflect the most current cost of a multiple source drug, or
- If a single provider agrees to a special price.

TN No. SPA # 17-002 <u>24-0014</u>	Approval Date June 2, 2017
Supersedes	
TN No. SPA # 16-004 <u>17-002</u>	Effective Date January 1, 2017 <u>June 1, 2025</u>

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: **DELAWARE**

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

Reimbursement Policy:

The lower of Usual and Customary or Actual Acquisition Cost (AAC) for Drug Reimbursement is derived using the methodology in the table below.

Category	Ingredient Cost	Professional Dispensing Fee
Brand Drug	NADAC	\$10
Generic Drug	NADAC	\$10
Drugs Without NADAC	WAC for legend and WAC-2% for non-legend; or a Delaware Maximum Allowable Cost (<u>DMAC</u>), whichever is lower.	\$10

340B Purchased Drug	AAC for dispensed drugs	\$10
	AAC for physician administered drugs	\$0
Contract 340B Pharmacy	Drugs acquired through the Federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies are not covered.	N/A
Drugs purchased by 340B entities enrolled with DMMA as utilizing public health service products, which based on specific conditions, must purchase drugs outside of the 340B inventory when that drug is not available or eligible for 340B purchase.	NADAC	\$10
Federal Supply Schedule	AAC	\$10
Drugs Acquired at Nominal Price	AAC	\$10
Specialty Drugs-Mailed	AAC (Invoice price) <u>NADAC, DMAC or AAC, whichever is lower</u>	\$27
Drug Not Dispensed by Retail Pharmacy	<u>NADAC, DMAC or WAC, whichever is lower.</u>	\$10
Physician Administered Drugs	AAC based on invoice price if maximum unit cost is greater than or equal to \$50. For drugs where the maximum cost is less than \$50, the cost will be based on invoice price or the Medicare fee schedule. <u>NADAC, DMAC, WAC, whichever is lower. Medications below \$50, the cost will be based on the invoice price or the Medicare fee schedule.</u>	N/A
Clotting Factor	AAC (Invoice Price) <u>DMAC or AAC, whichever is lower</u>	\$27
Investigational Drugs (when prior authorized; as a general rule not covered products)	AAC	\$10
<u>Cellular and Gene Therapy Medication List</u>	<u>AAC or ASP + 6%, whichever is lower.</u>	<u>N/A</u>

TN No. SPA ~~23-0003~~ 24-0014

Approval Date ~~December 19, 2023~~

Supersedes

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28 DE Reg. 358 (11/01/24) (Prop.)