# DEPARTMENT OF HEALTH AND SOCIAL SERVICES

## DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

## FINAL

### ORDER

### Cellular and Gene Therapy

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to amend Title XIX Medicaid State Plan Attachment 4.19-B pages 14 and 14a regarding Cellular and Gene Therapy, specifically, to change pricing logic for clotting factors and specialty medications to control cost. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Del.C.** §10114 and its authority as prescribed by 31 **Del.C.** §512.

The Department published its notice of proposed regulation changes pursuant to 29 **Del. C.** §10115 in the November 2024 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by December 2, 2024, at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

**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.

**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.

**Statutory Authority**

- Executive Order 14087
- CMS Rule 2434-F

**Purpose**

The purpose of this 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 at 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 gave public notice and provided an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments were to have been 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 to provide any 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 Statement**
There is no anticipated fiscal impact.

**Summary of Comments Received with Agency Response and Explanation of Changes**

**Comment:** There were comments supporting the proposed changes.

**Agency response:** DMMA appreciates the support.

DMMA is pleased to provide the opportunity to receive public comments and greatly appreciates the thoughtful input given by:
- State Council for Persons with Disabilities (SCPD)
- Governor's Advisory Council for Exceptional Citizens (GACEC)

**IMPACT ON THE STATE'S GREENHOUSE GAS EMISSIONS REDUCTION TARGETS AND RESILIENCY TO CLIMATE CHANGE:**

The DMMA Division Director has reviewed the proposed regulation as required by 29 Del. C. §10118(b)(3) and has determined that if promulgated, the regulation would have a de minimis impact on the State's resiliency to climate change because neither implementation nor compliance with the regulation would reasonably involve the increase in greenhouse gas emissions.

**FINDINGS OF FACT:**
The Department finds that the proposed changes as set forth in the November 2024 *Register of Regulations* should be adopted.
THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding Cellular and Gene Therapy, specifically, to change pricing logic for clotting factors and specialty medications to control cost and shall be final effective January 11, 2025.

12/10/2024 | 4:36 PM EST
Date of Signature

Josette D. Manning Esq., Secretary, DHSS



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.



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.

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 (DMAC), 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)~~ NADAC, DMAC or AAC, whichever is lower | $27 |
| Drug Not Dispensed by Retail Pharmacy | NADAC, DMAC or WAC, whichever is lower. | $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.~~<br>NADAC, DMAC, WAC, whichever is lower. Medications below $50, the cost will be based on the invoice price or the Medicare fee schedule. | N/A |
| Clotting Factor | ~~AAC (Invoice Price)~~ DMAC or AAC, whichever is lower | $27 |
| Investigational Drugs (when prior authorized; as a general rule<br>not covered products) | AAC | $10 |
| Cellular and Gene Therapy Medication List | AAC or ASP + 6%, whichever is lower. | N/A |