



**Department
of Health**

Transition of Clotting Factor Products and Services from Medicaid Fee-for-Service to Medicaid Managed Care

June 2019 - Updates guidance issued in May 2017

Effective July 1, 2019

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Office of Health
Insurance Programs

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**NEW YORK STATE DEPARTMENT OF HEALTH
OFFICE OF HEALTH INSURANCE PROGRAMS**

Transition of Clotting Factor Products and Services from Medicaid Fee-for-Service to Medicaid Managed Care

Summary of Changes

This guidance, issued in June 2019, updates clotting factor guidance issued in May 2017.

Overview

- Added clarification that this policy does not pertain to drugs used in the treatment of bleeding disorders.

Continuity of Care/ Transitional Care

- The Department has decided to continue the two-year transition policy.

Responsibilities of MMC Plans

- Language has been added to clarify that MMC plans must continue to follow the New York State Department of Health (Department) approved criteria standards for the authorization and utilization management of clotting factor products and services.
- Language has been added to clarify that any changes in an MMC plans criteria for the authorization and utilization management of clotting factor products and services must be submitted to the Department for review and approval prior to use.

Network Requirements

- This section has been updated to require that one of the two clotting factor providers an MMC plans must contract with per county must be a Hemophilia Treatment Center (HTC), and the other must be a pharmacy.
- This section has been updated to require that if a clotting factor provider serves five or more of an MMC plans enrollees, the plan must contract with said provider.

Overview

Effective July 1, 2017, clotting factor products will be included in the Medicaid managed care benefit package. On the effective date of transition, Medicaid Managed Care (MMC) plans will be required to cover medically necessary clotting factor products and associated services for MMC plan enrollees and to reimburse clotting factor providers for provision of products and services to plan enrollees. This change applies to all MMC plans, including mainstream Medicaid Managed Care Plans (MMCP), HIV Special Needs Plans (HIV SNP) and Health and Recovery Plans (HARP). Prior to the July 1, 2017 transition date, clotting factor products for MMC enrollees, and provided through Medicaid-enrolled pharmacies and clinics in all non-inpatient settings, including in the home, were billed to Medicaid Fee-for-Service (FFS). Clotting factor products administered during an inpatient stay prior to the transition date were covered by the enrollee's MMC plan; after the transition date, MMC plans will continue to be responsible for such coverage as part of the hospital All Patient Refined-Diagnosis Related Groups (APR-DRG) or per diem rate. The standard of care and treatment of hemophilia and other bleeding disorders is a continually changing field and should be driven by good clinical rationale and utilize an individualized plan of care. There shall be no interruption in the provision of medically necessary clotting factor products

and services as a result of this transition. This policy does not pertain to drugs that are used in the treatment of bleeding disorders.

The following guidelines identify the scope of benefits, continuity of care, MMC plan and provider responsibilities, data and rate adjustment, and network requirements.

I. Scope of Coverage

- a. MMC plans will be responsible for covering the following for their enrollees:
 - i. All FDA-approved human plasma-derived clotting factors and recombinant clotting factors.
 - ii. Administration of clotting factor products in all non-inpatient settings, including the home, and associated patient-specific care management.

II. Continuity of Care/Transitional Care

- a. Current MMC plan enrollees receiving clotting factor are permitted to keep their current provider of blood factor for two (2) years after the July 1, 2017 transition date.
- b. After the July 1, 2017 transition date, individuals who are newly enrolled in MMC plans are permitted to keep their current provider of clotting factor for two (2) years from their effective date of enrollment.
- c. For current MMC plan enrollees receiving non-inpatient clotting factor, MMC plans will immediately authorize medically necessary clotting factor products and services in accordance with the enrollee's individualized service plan and will not initiate a change to the enrollee's individualized service plan for these services and products for at least ninety (90) days from the July 1, 2017 transition date.

III. Responsibilities of MMC Plans

- a. MMC plans are responsible for notifying affected enrollees of the clotting factor benefit package change at least thirty (30) days in advance of the transition date.
- b. MMC plans are responsible for oversight of service planning and service delivery for enrollees receiving clotting factor products, including continuity of care. Plans must coordinate with providers to develop an individualized care plan and patient-specific care management to ensure that enrollees have appropriate and timely clotting factor supplies and services. Plans must ensure provision of clotting factor benefit package services in accordance with Attachment A, *Medicaid Managed Care Requirements for Accessing and Authorization of Clotting Factor Services*.
- c. To ensure the availability of services and continuity of care for enrollees receiving clotting factor products and services, MMC plans must contract with appropriately credentialed service providers and/or enter into single case agreements with providers and/or allow enrollees to access the necessary services from appropriate providers on an out-of-network basis. Continuity of care/transitional care guidelines as outlined in Section II. above apply.

- d. MMC plans will reimburse clotting factor providers for medically necessary clotting factor products and services provided to plan enrollees.
- e. MMC plans will submit their criteria for authorization and utilization management of clotting factor products and services to the Department for approval prior to use.
 - i. MMC plans that have already submitted their criteria to the Department and received approval, must continue to follow their criteria for the authorization and utilization management of clotting factor products and services as approved by the Department.
 - ii. Any changes to an MMC plans criteria for the authorization and utilization management of clotting factor products and services must be submitted to the Department for review and approval prior to use.
- f. MMC plans must designate a clotting factor liaison and provide direct contact information for the liaison to providers of clotting factor products and services. The MMC plan liaison will work with the provider and assist in navigating the process of obtaining authorization for clotting factor product and services, billing, and other issues that may arise throughout the transitional period. The MMC plan liaison will serve as the link within the MMC plan to assure timely access to clotting factor product and services for managed care plan enrollees.

IV. Responsibilities of Providers of Clotting Factor Products and Services

- a. Providers are responsible for coordinating with MMC plans to develop an individualized care plan and patient-specific care management to ensure that enrollees have appropriate and timely clotting factor supplies and services.
- b. On and after the transition date, providers will submit claims to MMC plans for clotting factor products and services provided to MMC enrollees according to the plans' billing guidelines.
- c. For MMC plans whose pharmacy benefit is managed through a subcontractual relationship, pharmacy providers supplying clotting factor to enrollees may be required to directly bill the pharmacy benefit management subcontractor as indicated by MMC plan.

V. Utilization Data and MMC Plan Rate Adjustment

- a. Enrollee-specific clotting factor utilization data is available on the monthly Medicaid Fee-for-Service pharmacy feed currently provided to MMC plans.
- b. Adjustments will be made to the pharmacy and medical components of the 2017 MMC plan premiums to accommodate the transition of clotting factor to Managed Care.
- c. Clotting factor will be added to the existing high cost drug pool which compensates MMC plans with a disproportionate share of high cost drugs utilization.

VI. Network Requirements

- a. The Department has provided providers with a list of MMC plans whom providers may contract with to provide clotting factor products and services.
- b. MMC plans must contract with a minimum of two clotting factor providers per county for provision of clotting factor products and services. An exception to this requirement may be allowed if an MMC Plan is able to document diligent efforts to identify service providers and there is only one willing and qualified entity available to provide services in a geographic area, such as in a rural area. Where contracts do not exist, MMC plans must permit enrollees to access services through out-of-network arrangements.
 - i. One of such providers must be an HTC, and the other a pharmacy.
 - ii. If a provider serves five or more of an MMC plan's enrollees, the MMC plan must contract with said provider.

VII. Billing and Payment

The transition of clotting factor products into managed care will not result in additional costs to the State Medicaid Program.

- a. The transition will include adjustment to MMC plan premium rates by the State to reflect the Medicaid fee for service (FFS) expenditures of clotting factor products for plan enrollees.
- b. It is expected that MMC plans and providers will negotiate contracts with reasonable payment terms and conditions reflecting overall cost neutrality.
- c. If a MMC plan and provider cannot reach agreement on payment terms, the MMC plan will offer a rate equivalent to the Medicaid FFS payment. Should the clotting factor provider then not agree to the Medicaid FFS equivalent rate, the MMC plan may facilitate the enrollee's transfer to another provider prior to the end of his or her two-year Continuity of Care/Transitional Care period. The MMC plan must ensure there is no gap in service provision and all other continuity of and access to care requirements in this policy are followed.
- d. Providers participating in the 340B program will not be required to dispense 340B clotting factor products. If a provider dispenses a 340B clotting factor product, the provider must identify the 340B clotting factor product on the claim to the MMC plan. The MMC plan must then identify 340B products in encounter reporting to the State.

ATTACHMENT A

Medicaid Managed Care Requirements for Accessing and Authorization of Clotting Factor Services

General policy: To ensure uninterrupted and person-centered care management for enrollees in need of Benefit Package clotting factor products and services, Medicaid Managed Care (MMC) plans will provide medically necessary clotting factor products and services in accordance with the following:

I. Care Management

- a. The Person Centered Services Plan will meet the requirements of Section 10.35 of the Model contract and be inclusive of the individual service plan developed by the enrollee's provider of clotting factor products and services.
- b. Regardless of the reason for disenrollment, upon notice of or request for disenrollment, the MMC plan must prepare a written discharge plan for an enrollee for whom a treatment plan has been established to assure continuity of care at the time of disenrollment.
 1. With the enrollee's consent, information will also be provided on and referrals provided to case management resources and primary care providers and providers of clotting factor products and services.
 2. The discharge plan should be provided to the enrollee, and with the enrollee's consent, to his/her legal guardian where applicable, and to his/her designated care provider within fifteen (15) days of the notice of, or request for disenrollment.

II. Transitional Care

- a. For new enrollees previously in FFS, notwithstanding any benefit- or population-specific FFS to MMC transitional care policy issued by the Department, MMC plans will immediately authorize medically necessary clotting factor products and services in accordance with the enrollee's individualized service plan and will not initiate a change to the enrollee's individualized service plan for these services and products for ninety (90) days from the effective date of enrollment, or until the MMC plan's person centered services plan is in place, whichever is later.
 1. If the individualized service plan is not available, the MMC plan will accept a valid medical order or prescription to authorize medically necessary clotting factor products or services, and work with the enrollee's provider to develop the individualized service plan, without initiating a change to the enrollee's type, level or quantity of clotting factor products or services for ninety (90) days from the effective date of enrollment, or until the MMC plan's person centered services plan is in place, whichever is later.

III. Authorization Standards

- a. MMC plans will make a service authorization determination for clotting factor products and services as fast as the enrollee's condition requires and within expedited service authorization review timeframes described in the Model Contract Appendix F.1(3).

- b. When the need for clotting factor products and services presents and/or an urgent referral is made by a provider during non-business hours, and the MMC plan cannot be reached to request authorization, the provider of clotting factor products and services will request authorization with all necessary information by the next business day. The MMC plan may not deny clotting factor product and services provided under these circumstances for lack of medical necessity or prior authorization, while the MMC plan determination is pending.