

NYSDOH Office of Health Insurance Programs
Criteria Standards for the Authorization and Utilization Management
of Clotting Factor Products and Services

Each Medicaid Managed Care (MMC) Plan's policy, procedures and coverage criteria for the authorization and utilization management of clotting factor products and services will be reviewed by NYSDOH (the Department) to ensure its clinical appropriateness. Such criteria must be approved by the Department before it may be used for Service Authorization Request determinations.

I. Submission

- A. Each MMC Plan that chooses to adopt criteria for the authorization and utilization management of clotting factor products and services must submit the criteria (and any subsequent amendment to such criteria) electronically to the Department's Bureau of Managed Care Certification & Surveillance (BMCCS) BML: bmccsmail@health.ny.gov *Attention: Medical Director – Clotting Factor Standards* for Department review and approval prior to use.
- B. The submission must include the MMC Plan's Chief Medical Officer's approval of its criteria for the authorization and utilization management of clotting factor products and services.
- C. The MMC Plan's submission must clearly demonstrate compliance with the requirements of the *Transition of Clotting Factor Products and Services from Medicaid Fee-for-Service to Medicaid Managed Care* policy paper, and all applicable Medicaid managed care program requirements.
- D. Any change to a MMC Plan's 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.

II. Criteria requirements

To be considered satisfactory, a MMC Plan's criteria for the authorization and utilization management of clotting factor products and services must, at a minimum:

- A. Be based on evidenced-based practice and/or nationally established clinical practice guidelines, when available (such as those published by the World Federation of Hemophilia and the National Hemophilia Foundation – Medical and Scientific Advisory Council), and developed in compliance with Public Health Law Article 49;
- B. Be aimed at the rapid provision and the effective replacement of the deficient clotting factor;
- C. Consider the best interests of the enrollee's health, including the unique medical profile and unique medical needs, when determining the appropriateness of requested clotting factor products, treatment strategies, and associated services;

- D. Be aligned with a comprehensive multidisciplinary integrated care model for the treatment of bleeding disorders that promotes the physical and psychosocial health of the enrollee, and addresses the wide-range of needs that are usually associated with bleeding disorders;
- E. Consider the provider's clinical recommendations, the enrollee's person centered services plan, and the provider's individual service plan when determining the appropriateness of requested clotting factor products, treatment strategies, and associated services;
- F. Not include a step therapy or a fail-first protocol in its criteria for the authorization of clotting factor products;
- G. Reflect that the MMC Plan is responsible for covering all FDA-approved human plasma-derived clotting factors and recombinant clotting factors, and that clotting factor product choice should be based on the unique medical profile and the unique medical needs of each enrollee;
- H. Reflect that the MMC Plan is responsible for covering all the medically necessary ancillary supplies and services required for the administration of the prescribed clotting factor product;
- I. Reflect that the MMC Plan is responsible for covering the administration of clotting factor products in all settings (inpatient and outpatient), including the home;
- J. Consider the importance of continuity of care, including assurance that no enrollee with a valid prescription is left without medically indicated clotting factor product while a service authorization determination is pending;
- K. Ensure that decision makers on service authorization denials and action appeals have clinical expertise in treating bleeding disorders;
- L. Ensure that medical necessity service authorization denials and action appeals are peer-to-peer — that is, the credential of the decision maker on denials, grievances, and appeals must be at least equal to that of the health care professional prescribing the clotting factor product or service;
- M. Include processes and procedures for communicating its criteria for the authorization and utilization management of clotting factor products and services to enrollees and their providers.

III. Requirements for MMC Plan Authorization Policy and Procedures

- A. Authorization and Utilization Management Criteria must be implemented in compliance with all relevant statutes and regulations, including but not limited to New York State Public Health Law Article 49.
- B. All service authorization determinations must be made pursuant to the enrollee's person centered services plan and in coordination with the enrollee's providers.

- C. Before issuing an adverse determination regarding a clotting factor product or service prescribed by the enrollee's health care professional treating the blood clotting disorder, the MMC Plan must make reasonable attempts to engage in a peer-to-peer discussion with that health care professional to understand the reasons behind the need for prescribing the requested clotting factor product or service. As per paragraph G below, the time frame to issue a determination is not changed while the MMC Plan attempts to contact the prescriber. The MMC Plan may extend the review time in accordance with the MMC/FHP/HIV SNP Model Contract, if requested by the provider or enrollee, or if such extension is in the best interest of the enrollee.
- D. The MMC Plan should consult with a licensed Hematologist as part of any appeal review of an adverse determination regarding clotting factor products and services for the treatment of blood clotting disorders.
- E. The MMC Plan must meet all NY State Medicaid emergency prescription drug supply requirements.
- F. The MMC Plan must have appropriate mechanisms in-place to ensure that an enrollee, who has a prescriber's order for a clotting factor product, receive a temporary supply of the requested clotting factor product (per the prescriber's order), if the clotting factor is not available to the enrollee while a service authorization determination is pending.
- G. All service authorization determinations for clotting factor products and services must be determined as fast as the enrollee's condition requires and within expedited service authorization review timeframes described in the MMC/FHP/HIV SNP Model Contract Appendix F.1(3).
- H. 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, and the provider of clotting factor products and services requests authorization with all necessary information by the next business day, the MMC Plan will not deny clotting factor product and services provided under these circumstances for lack of medical necessity or prior authorization, while the service authorization determination is pending;
- I. Service Authorization determinations must consider the following continuity of care requirements as provided in the *Transition of Clotting Factor Products and Services from Medicaid Fee-for-Service to Medicaid Managed Care* policy paper:
 - i. Current MMC plan enrollees receiving clotting factor for the treatment of clotting factor disorders are permitted to keep their current provider of blood factor for two (2) years after the July 1, 2017, transition date.
 - ii. Individuals who are newly enrolled in MMC plans after the July 1, 2017, transition date, are permitted to keep their current provider of clotting factor for two (2) years from their effective date of enrollment.
 - iii. 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.

- iv. For new MMC Plan enrollees, previously in FFS, notwithstanding and 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.
 - 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.