



Department of Health

Transition of Clotting Factor Products and Services into Medicaid Managed Care

Frequently Asked Questions

Contracting

1. If Plans are required to contract with two providers in each county, do Plans need to contract with providers who treat hemophilia – hematologists – or specifically hemophilia clinics?

Plans are required to contract with two providers of outpatient clotting factor product.

1a. Please confirm that providers here are also pharmacies?

These providers may or may not be pharmacies.

1b. Are we required to have all these providers in the network?

Plans are required to offer contracts to providers their plan enrollees are currently utilizing for clotting factor product and services, and otherwise meet the network standard described in the policy.

1c. Do they have to be credentialed for our/PBM network?

This decision is at the discretion of the Plan.

1d. Do they have to be allowed to dispense other drugs as well?

This decision is at the discretion of the Plan.

2. Does the MCO have to pay whatever the provider charges or do they negotiate pricing?

It is expected that Medicaid Managed Care (MMC) plans and providers will negotiate contracts with reasonable payment terms and conditions reflecting overall cost neutrality. 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.

Claims and Reimbursement

3. Can you please provide the Medicaid Fee Schedule for blood clotting factors? i.e. What are we required to pay?

Please see links provided:

http://www.health.ny.gov/health_care/medicaid/redesign/2017/2017-03-06_ndc.htm

http://www.health.ny.gov/health_care/medicaid/redesign/2017/2017-03-06_j-code.htm

4. How will providers be reimbursed for 340B clotting factor when it is carved into Managed Care? Will the managed care plans use the same reimbursement policies and rates that are used in the Fee-for-Service (FFS) program?

Pursuant to Section VII of the Clotting Factor Guidelines found at:

[http://www.health.ny.gov/health_care/medicaid/redesign/2017/2017-](http://www.health.ny.gov/health_care/medicaid/redesign/2017/2017-05_clotting_factor_guidelines.htm#overview)

05_clotting_factor_guidelines.htm#overview, it is expected that Medicaid Managed Care (MMC) plans and providers will negotiate contracts with reasonable payment terms and conditions reflecting overall cost neutrality. 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.

As established by current policy, providers using 340B products for Medicaid members will need to continue to identify that they are billing for a 340B product, per the guidelines summarized in the December, 2016 Medicaid Update, which can be found at:

http://www.health.ny.gov/health_care/medicaid/program/update/main.htm

5. Does clotting factor fall under the “prescriber prevails” provision in Managed Care, under the category of *Hematological Agents*”?

No, clotting factor does not fall under the “prescriber prevails” provision. Hematological Agents that fall under this provision can be found by accessing the Medicaid FFS Preferred Drug List at: https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PDL.pdf

Miscellaneous

6. What clotting factor products will be covered by Medicaid?

All FDA-approved human plasma-derived clotting factors and recombinant clotting factors.

7. If services are supposed to be kept the same for a two-year period, can you advise as to how plans are expected to keep the same services if they transfer to another plan? Would plans be required to put together a “discharge” plan? If so how is this information to be provided to the new plan? Most of the time when our members transfer to another plan, we have no way of knowing where they transfer to. Is there going to be a way for tracking these members?

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. 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. 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.

8. Will MCO plans be allowed to apply formularies, PDL's, prior authorization, and/or step therapy protocols to clotting factor, especially if they manage factor as a pharmacy benefit? If so, what guidelines will DOH establish for these different practices?

Please refer to the “Criteria Standards for Authorization and Utilization Management of Clotting Factor Products and Services” guidance document. All criteria for clotting factor must be approved by the Department prior to use. The use of clotting factor products and services in the treatment for bleeding disorders should be individualized, and consider the enrollee’s unique medical profile and unique medical needs, when determining the appropriateness of the requested clotting factor products and associated services.

9. Section II, part C of the 2/1 DOH document refers to MCO plans being able to initiate changes to enrollee's individualized service plans after 90 days; what is an "individualized service plan", and what changes can MCO plans initiate?

The individualized service plan is the enrollee’s unique treatment plan that was developed by his/her treating provider. If the plan elects to review the individualized service plan for appropriateness, the plan must follow the guidance issued in the “Criteria Standards for the Authorization and Utilization Management of Clotting Factor Products and Services” guidance document.

10. What if the patient receives other medications (not factor) from this provider would they be allowed to continue? Or will they have to use a different provider. This brings up the question overall continuity of care?

In general, all other continuity of care provisions already in place would apply to other benefits—including those in the model contract for pharmacy continuity for new enrollees (10.32(c)). The transition of clotting factor should not disrupt access to other services already provided under the health plan.

11. How does the contract address transition (e.g. requirements to provide continuous coverage for blood products)? Is there anything else we should require beyond what is in the contract?

Guidance authorized under model contract can be found at the following link.

http://www.health.ny.gov/health_care/medicaid/redesign/2017/2017-05_clotting_factor_guidelines.htm

12. For bleeding disorders other than hemophilia, or off label use, when clotting factor is not the first line treatment according to the accepted standard of care, can plans require fail first or step therapy of the first line treatment?

Pursuant to Section II.F of the Criteria Standards for the Authorization and Utilization Management of Clotting Factor Products and Services, plans should not include a step therapy or a fail-first protocol in its criteria for the authorization of clotting factor products. This means that prior authorization or denial for all clotting factor claims should not be used as a vehicle for evaluating first line therapy options or off-label use. However, plans may use prospective systematic or clinical editing that narrows the number of claim denials or prior authorization requests to only those patients for whom an evaluation would be most appropriate, consistent

with evidenced-based practice and/or nationally established clinical practice guidelines.

As referenced in Section I.A. of the Criteria Standards for the Authorization and Utilization Management of Clotting Factor Products and Services, plans must submit criteria (prospective or retrospective) to the Department's Bureau of Managed Care Certification & Surveillance (BMCCS), for review and approval.

13. Please clarify the ‘unique medical needs’ that are referenced in Section II.G. If the intent is that the determination must be based on, or consider, the personal preference of the member, please so state.

“Unique medical needs” (in the context of Section II.G of the “Criteria Standards for Authorization and Utilization Management of Clotting Factor Products and Services” guidance document) means that the Plan must take into consideration that the choice of the clotting factor product should be based on the enrollee’s medical needs, which are in-turn based on that enrollees unique medical profile. Enrollees with unique medical profiles (age, venous access status, inhibitor titer status, activity level, etc.), have unique medical needs that should dictate their clotting factor product characteristics (clotting factor purity, clotting factor immunogenicity, clotting factor half-life, etc.). “Unique medical needs” does not equal “personal preferences”. However, the patient should always be involved in his/her treatment plan.

14. Section III. C. Does this apply to off-label requests for clotting factor or clotting factor prescribed only for a bleeding disorder or hemophilia? This provision should be revised to indicate that the plan must attempt to contact the prescriber and request a peer-to-peer discussion at least 24 hours before making an adverse determination. There has to be a timeframe that allows the plan to move forward with the adverse determination if the prescriber cannot be reached or refuses to engage in a peer-to-peer discussion.

The “Criteria Standards for Authorization and Utilization Management of Clotting Factor Products and Services” guidance document applies to clotting factor products prescribed for the treatment of bleeding disorders.

Section III. C. already states that Plans must attempt to contact the prescriber and request a peer-to-peer discussion before making an adverse determination.

Plans should follow the provisions set forth in the Medicaid managed care model contract if they are unable to engage the prescriber in a peer-to-peer discussion before making an adverse determination. Reasonable attempts are defined as at least 3 attempts with 2 different mechanisms of communication. However, authorization procedures limit the timeframe that a Plan may wait before issuing a determination. The Plan must make a determination within the maximum times permitted under the Medicaid managed care model contract – expedited time: 3 business days with possible extension of up to 14 days if it is in the enrollee’s best interest to delay the determination in order to gather/wait for more information.

15. We have a concern regarding the wording of one of the requirements noted in the updated Clotting Factor guidelines on the Department’s website, linked here: https://www.health.ny.gov/health_care/medicaid/redesign/2017/docs/2017-05_clotting_factor_guidelines.pdf The concern is related to p. 5 (p. 6 of the PDF), where it talks about PCSP’s in the Care Management section; “*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.*”

Concerns:

1)PCSP’s are for long-term care members, not the chronically ill.

The concern above is not accurate. Person Centered Services Plan (PCSP) is not limited to individuals with Long Term Services and Supports (LTSS). As per Federal rule 42 CFR 438.208(c)(3), service plans were expanded to populations with special health care needs as defined by the State. Plan enrollees, with clotting factor disorders, should have PCSPs that fulfill the minimum requirements stated in Section 10.35 of the Model Contract, especially Section 10.35 (b).

2)Care Plans are not Person-Centered Service Plans, but they are specific to a patient/individual.

A Person Centered Services Plan is a written description in the Care Management record of participant-specific health care goals to be achieved and the amount, duration, and scope of the covered items and services to be provided to a participant in order to achieve such goals.

3)PCSP’s are not standardized.

At this time, Person Centered Services Plans are not standardized. Potential PCSP standardization is a topic of possible discussion in the future.

16. What is the Plans responsibility if an enrollee refuses care management?

As directed in the Clotting Factor Guidelines; Medicaid Managed Care (MMC) plans are responsible for oversight of service planning and service delivery for enrollees receiving clotting factor products, including continuity of care. Therefore, if an enrollee refuses care management due to their care being managed through a Hemophilia Treatment Center (HTC) or for any other reason, it is the responsibility of the MMC plan to document their outreach efforts and the enrollee’s refusal. Care management outreach efforts must be re-attempted at least annually or upon significant change, such as notification that the enrollee is no longer receiving care management through an HTC. To ensure that the enrollee is making an informed decision regarding the management of their clotting factor products and services, MMC plans are to educate the enrollee on the importance of clotting factor care management and the benefits of a Person Centered Services Plan.