

Title: Informed Consent for Hysterectomy and Sterilization	Division: Medical Management
Policy Number: QMD-109	Department: Quality Management
Effective Date: 6/1/2022	Unit:
Initial Effective Date: 05/25/99	LOB: Medicaid

1. POLICY:

MetroPlus Health Plan providers will comply with New York State Department of Health and Mental Hygiene (NYSDOHMH) informed consent guidelines for hysterectomy and sterilization as found in 42 CFR, Part 441, Sub Part F and 18 NYCRR Section 505.13.

2. RESPONSIBLE PARTIES:

Providers: must conform to informed consent guidelines.

Provider Network Operations Department: staff is responsible for reinforcing to providers their requirement to conform to informed consent guidelines at provider orientations and through the provider manual.

Quality Management Department: Senior Associate Director Quality Management monitors compliance with this policy.

3. AFFECTED DEPARTMENTS:

Provider Network Operations
Quality Management

4. DEFINITIONS:

Hysterectomy: Medical procedure or operation for the purpose of removing the uterus.

Sterilization: Any medical procedure, treatment or operation for the purpose of rendering an individual permanently incapable of reproducing or having children.

5. PROCEDURE:

- A. Providers who perform hysterectomies or other sterilization procedures are required to obtain informed consent from any MetroPlusHealth Plan member undergoing a hysterectomy or other sterilization procedure.
- B. In the case of a hysterectomy, MetroPlusHealth Plan will authorize this procedure if there are appropriate clinical indications.
- C. A member undergoing a hysterectomy must be notified verbally and in writing that the procedure will render her permanently sterile. She or her authorized representative must

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sign the Sterilization Consent Form (Attachment A) and the Acknowledgement of Hysterectomy Information Form (Attachment B).

- D.** This requirement is only waived if the hysterectomy was performed in a life threatening (emergency) situation or when evidence exists that the member was sterile prior to the procedure. If either situation occurs, then the surgeon’s attestation must be completed stating that one of these circumstances existed.

- E.** MetroPlus Health Plan also covers sterilization (as defined as any procedure or treatment performed solely for rendering the member incapable of reproducing), however the following restrictions apply:
 - i. Member must be at least 21 years of age at the time consent is obtained.
 - ii. Member must be mentally competent and able to consent to sterilization.
 - iii. Member must not be institutionalized (involuntarily confined to a correctional, rehabilitation, or mental illness treatment facility or voluntarily confined to a mental illness treatment facility).
 - iv. Informed consent must not be obtained during labor, childbirth, abortion (or abortion request), or under the influence of alcohol or any substance that alters the members mental state.
 - v. Translation services must be provided if the member does not speak the language used on the consent form or by the person obtaining informed consent.
 - vi. Arrangements must be made for deaf, blind, or otherwise disabled members.
 - vii. A witness must be present if the informed consent is obtained in NYC as required by New York City Local Law No. 37 (1977).
 - viii. At least 30 days, but no more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed since he/she gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

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- ix. In New York City, members must sign a reaffirmation statement upon admission, acknowledging an understanding of the consequences of sterilization and reaffirming their desire to have the procedure.

F. Specific Disclosures: Informed Consent

i. Informing the Individual:

The person who obtained consent for the sterilization procedure must be available to answer questions and provide all requested information and advice in addition to providing the form and informed consent. The following issues must be discussed with the member seeking sterilization at least thirty (30) days before the procedure is performed:

- a. Member’s right to withdraw consent at any time prior to the procedure without jeopardizing any future treatment or federally subsidized benefit.
 - b. Alternative methods of family planning and birth control.
 - c. Irreversibility of the sterilization procedure.
 - d. Detailed and thorough explanation of the procedure to be performed.
 - e. Full description of the associated risks, side effects, and discomforts (including those associated with any anesthesia to be used).
 - f. Full explanation of the benefits or advantages to be expected after undergoing the procedure.
 - g. Explanation that the procedure will not be performed for at least thirty (30) days except in cases of premature delivery or emergency abdominal surgery.
- ii. Suitable arrangements were made to ensure that the information specified in this section is effectively communicated to any individual who is blind, deaf, or otherwise handicapped;
 - iii. An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent;

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- iv. The individual to be sterilized was permitted to have a witness of his or her choice present when consent was obtained;
 - v. The consent form requirements of § 441.258 were met:
 - a. Required signatures: Individual to be sterilized, interpreter if one was provided, person who obtained the consent and the physician who is performing the sterilization procedure.
 - vi. Any additional requirement of State or local law for obtaining consent, except a requirement for spousal consent, was followed.
 - vii. Informed consent may not be obtained while the individual to be sterilized is:
 - a. In labor or childbirth
 - b. Seeking to obtain or obtaining an abortion
 - c. Under the influence of alcohol or other substances that affect the individual's state of mind.
- G.** MetroPlusHealth Provider Network staff will conduct provider orientation for OB/GYN's and Urologists and/or other doctors that perform these types of procedures. Providers will be given a provider manual and provider orientation material. The provider manual contains information regarding informed consent for hysterectomy and sterilization.
- H.** On an annual basis the Quality Improvement Specialist from the Quality Management Department will outreach to participating providers who have been identified via claims to have performed sterilization(s) and monitor compliance with the informed consent procedures for hysterectomy and sterilization as specified in 42 CFR, Part 441, Sub Part F and 18 NYCRR Section 505.13.
- I.** A letter will be sent to the Provider requesting the member's signed consent form be sent to the Quality Improvement Specialist (Attachment C).
- J.** If standards are not met Provider Network will outreach to individual providers to discuss the importance of complying with informed consent procedures for hysterectomy and sterilization and provide re-education. Providers will be re-evaluated after a period of 6 months and if still non-compliant will be presented at

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the Credentialing Subcommittee for further action and reported to the Quality Management Committee (QMC).






6. REGULATORY REFERENCES:

Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan/Health & Recovery Plan Model Contract March 1, 2019: Section 35; 35.7
 Informed Consent: 42 CFR, Part 441, Sub Part F
 Informed Consent: 18 NYCRR Section 505.13

7. CROSS REFERENCES:

N/A

8. ATTACHMENTS:

Title	Attachment
Attachment A: LDSS-3134 Sterilization Consent Form	 Sterilization Consent Form.pdf
LDSS-3134 Sterilization Consent Form (Spanish)	 Sterilization Consent Form Spani
Attachment B: LDSS-3113- Acknowledgment of Hysterectomy Information	 Acknowledgement of Hysterectomy Infc
LDSS-3113- Acknowledgment of Hysterectomy Information (Spanish)	 Acknowledgement of Hysterectomy Infc
Attachment C: Letter to Provider Requesting Signed Consent Form	 Provider Letter Hysterectomy-Sterili:

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9. REVISION LOG:

REVISIONS	DATE
Included process to monitor hysterectomy and sterilization consent forms	10/7/15
Updated consent forms and revised monitoring process	2/18/16
Included definitions: Hysterectomy & Sterilization	2/22/21
Included Sterilization Consent Form in Spanish	5/16/22
Included Acknowledgment of Hysterectomy Information in Spanish	5/16/22
Date of Last Revision	6/1/22

10. APPROVALS:

Eleanor M. Sorrentino, RN
Deputy Executive Director,
Quality Management

Sanjiv Shah, MD
Chief Medical Officer

Date

Date