MetroPlus Health

Policy and Procedure

Title: Pasteurized Human Donor Milk	Division: Medical Management Department: Utilization Management
Approval Date: 3/30/2018	LOB: Medicaid, Medicare, HIV SNP, CHP, MetroPlus Gold, GoldCare I&II, Market Plus, Essential, HARP, UltraCare
Effective Date: 3/30/2018	Policy Number: UM-MP229
Review Date: 5/31/2023	Cross Reference Number:
Retired Date:	Page 1 of 4

1. POLICY DESCRIPTION:

Effective July 1, 2017, in accordance with the 2017-18 enacted state budget, pasteurized donor human milk (PDHM) for inpatient use is a covered benefit under the Medicaid program. MetroPlus Health also covers pasteurized donor human milk (PDHM) for all lines of business in accordance with this policy.

In accordance with an amendment to subdivision 2 of section 365-a of the Social Services Law, inpatient use of pasteurized donor human milk (PDHM), with fortifiers as medically indicated, requires a written medical order from a licensed medical practitioner.

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS:

Pasteurized Human Donor Milk (PDHM): Banked donor human milk that is screened, pooled, and pasteurized.

4. PROCEDURE:

A. Medically necessary PDHM is covered for inpatient use only for infants when the following criteria are met:

I. Have a documented birth weight of less than 1500 grams; or

II. Have a congenital or acquired condition that places the infant at a high risk of developing necrotizing enterocolitis (NEC) and/or infection.

B. Coverage of PDHM is for infants who meet the criteria outlined above and have one or more of the following conditions:

I. Are medically or physically unable to receive maternal breast milk or participate in breast feeding; or

II. Are unable to participate in breast feeding despite optimal lactation support; or

III. Are born to mothers whose breast milk isn't suitable for consumption due to the presence of certain substances or disease; or

IV. In cases where the mother is medically or physically unable to produce maternal breast milk at all or insufficient quantities.

5. LIMITATIONS/ EXCLUSIONS:

A. NYS tissue banking regulations require that PDHM be distributed only by tissue banks licensed by the NYS Department of Health and only with a written medical order. Of note, in order to provide medically fragile infants with PDHM, a hospital must first have a tissue bank license from the NYS Department of Health that includes human milk. Information on how to obtain such license is available at: https://www.wadsworth.org/regulatory/tissue-resources

B. Hospitals licensed to provide PDHM are required to bill using HCPCS code T2101 "Human breast milk processing, storage and distribution only." Hospitals should only bill for the amount dispensed, rounding up to the nearest mL (1mL = 1 unit for billing purposes). (Although T2101 is listed on the ordered ambulatory fee schedule, coverage is for inpatient use only (and not for outpatient use). Only inpatient providers can bill T2101.

C. Donated human breast milk to support and/or supplement or to replace breast feeding in the outpatient setting is considered not medically necessary as there is insufficient evidence to establish efficacy. According to EPSDT and CHIP officials, donated human breast milk or other services to promote breastfeeding is in need of additional research on their effectiveness in order to support medical necessity.

D. Authorization is required.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
T2101	Human breast milk processing, storage and distribution only (Only inpatient providers)

7. BACKROUND:

New York's Medicaid program reimburse hospitals outside the inpatient rate for pasteurized donor human milk (PDHM). PDHM coverage is only available for infants with a birth weight of under 1,500 grams or a condition that places them at high risk for developing necrotizing enterocolitis and/or an infection, and where maternal breast milk or breast feeding is not possible. To provide PDHM, hospitals must have a tissue bank license that includes human milk.

Hospitals can bill and be paid for PDHM at the actual acquisition cost for Medicaid fee-for-service patients. While Medicaid Managed Care Plans must cover PDHM, billing and payment procedures are determined by individual plans.

8. REFERENCES:

NY State DOH Division of Health Plan Medicaid Update July 2017 Volume 33, Number 7.
https://www.health.ny.gov/health_care/medicaid/program/update/2017/jul17_mu.pdf

NY State DOH Division of Health Plan Medicaid Update November 2017 Volume 33, Number 11.
https://www.health.ny.gov/health_care/medicaid/program/update/2017/nov17_mu.pdf

CHAPTER 55 Social Services Law, Title II, Section 365a, dd- pasteurized donor human milk (PDHM)
https://www.nysenate.gov/legislation/laws/SOS/365-A

New York State Perinatal Quality Collaborative (NYSPQC) Enteral Nutrition Improvement Project, Donor Milk Webinar Series, October 17, 2019 https://www.albany.edu/cphce/nyspqcpublic/NYSPQC-Enteral-Nutrition-Improvement-Project-CoachingCall-October2019-slides.pdf

REVISION LOG:

REVISIONS	DATE
Creation date	3/30/2018
Annual Review	3/15/2019
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Annual Review	5/31/2022
Annual Review	5/30/2023

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Approved: Glendon Henry Digitally signed by Glendon Henry Date: 2023.06.13 10:05:55 -04'00' **Date:**	**Approved:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.06.14 16:29:24 -04'00' **Date:**
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.