

Progesterone Guidance for the Prevention of Preterm Birth

The use of intramuscular progesterone (17p) for patients with a history of spontaneous preterm birth is a core performance expectation of all practices participating in the Pregnancy Medical Home program. The PMH Care Pathway, "[Progesterone Treatment and Cervical Length Screening](#)," provides clinical guidance on the use of this treatment. Several formulations of progesterone are covered by Medicaid under various structures, including the Point of Sale pharmacy program and Physician Drug Program.

Definitions

Point of Sale Pharmacy: The patient takes a prescription to the pharmacy, provides her Medicaid card, and receives the prescription. Pregnant patients are exempt from Medicaid co-pays for medications. Medicaid is charged for the prescription by the pharmacy at the time it is dispensed to the patient.

Physician Drug Program: The provider purchases the product up front (from a distributor, specialty pharmacy, etc.), then submits a claim to Medicaid when the product is administered to the patient. This program is often referred to as "buy and bill." For products only covered under Physician Drug Program, the patient cannot be sent to the pharmacy with a prescription, or she will be expected to pay out of pocket.

Intramuscular Progesterone (17p)

Commercial and Generic Hydroxyprogesterone Caproate (Makena™) is covered by NC Medicaid under the Physician Drug Program and Point of Sale Pharmacy Program.

- **Physician Drug Program:** The provider purchases a single or multi-dose vial of Makena™ from a distributor (CuraScript, McKesson Plasma and biologics, or TheraCom) and bills Medicaid for each dose administered using HCPCS code J1726. Current reimbursement is \$33.02/10mg (each dose contains 250mg) or \$825.50/dose. The practice is invoiced for the product 90 days after ordering, giving the provider time to administer and bill for these doses; this period may be extended to 120 days if needed. There is a "return for credit" program that allows providers to receive credit toward their next order for any medication that meets AMAG pharmaceuticals qualifications. The provider can purchase the product as "office stock" or labeled for a specific patient. When purchased as stock, the multi-dose vial can be used to treat more than one patient. A generic version of Makena™ is also available (hydroxyprogesterone caproate) and reimbursable by Medicaid using HCPCS code J1729. Current reimbursement is \$16.64/10mg or \$416.00/dose.
- **Point of Sale Pharmacy:** Makena™ and the generic product are available from a network of specialty and compounding pharmacies that have signed on as distributors of this product. The product is dispensed to a specific patient and Medicaid is charged at the time it is dispensed. Unused doses cannot be returned and cannot be used to treat other patients.

Compounded 17p is covered by NC Medicaid under the Physician Drug Program. The provider purchases the product from a compounding pharmacy in single-dose vials*. Per FDA guidance, the product must be prepared for a specific patient and labeled for that patient; "office stock" and multi-dose vials are not available at this time. The provider is invoiced at the time the product is shipped and bills Medicaid for each dose administered. Current reimbursement is \$19.80/dose. The NDC must be on the claim, and the product is billed using HCPCS code J3490.

Subcutaneous Progesterone

Makena™ can also be administered by a health care provider subcutaneously via an auto-injector once a week. It is available as a single-use auto-injector through a specialty distributor (CuraScript, McKesson Plasma and Biologics, or TheraCom) or Makena Care Connection**. The NDC must be on the claim and the product is billed using the HCPCS code J1726. Current reimbursement is \$33.02/10mg (each dose contains 275mg) or \$908.75 per dose. The auto-injector is also available via Point of Sale Pharmacy at select pharmacies. Patients needing to change from receiving subcutaneous progesterone to intramuscular progesterone do not need prior approval.

Vaginal Progesterone

As described in the PMH Care Pathway, this formulation may be recommended in patients with short cervix who do not have a history of spontaneous preterm birth. Currently, Prometrium™ capsules and Crinone™ gel are covered through the Point of Sale pharmacy program. Crinone™ gel is a non-preferred drug and **requires a prior authorization** using a drug request form from the following website: <https://www.nctracks.nc.gov/content/public/providers/pharmacy/forms.html>.

17P recommendations following the FDA Advisory Committee Decision

In Oct 2019, a Food and Drug Administration advisory committee recommended that approval be withdrawn for Makena™ – 17- α -hydroxyprogesterone caproate or “17P.” **This is not the final FDA ruling;** rather, the FDA will take this under advisement and provide a final ruling on the matter in the next several months.

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**Makena™ Care Connection

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