



Makena

The use of compounded hydroxyprogesterone caproate (CHC) has and continues to be a covered benefit by the Medicaid Managed Care Organizations and the Medicaid Fee-for-Service pharmacy program. Recently, Makena[®], also hydroxyprogesterone caproate, has received FDA approval to reduce the risk of preterm birth in women who are pregnant with a single baby and who have delivered a baby too early (preterm) in the past. Makena[®] is not intended for use in women with multiple gestations or other risk factors for preterm birth. Makena[®], which requires prior authorization and documentation of medical necessity, is also a covered medical benefit under the Medicaid Fee-for-Service program.

West Virginia Medicaid encourages providers to rely on their prior success with compounded CHC when making decisions for their patients. However, the compounded CHC product is not an FDA-recognized A-rated substitute for prescriptions written for Makena[®]. Therefore, compounded CHC cannot be substituted legally at the pharmacy level for prescriptions written for Makena[®]. To legally dispense the compounded CHC product when the prescription is written for Makena[®], a new prescription for CHC must be obtained from a physician.

As a matter of policy, Medicaid will pend for review any medical claims for Makena[®]. The physician will be required to demonstrate the medical necessity of the manufactured product, Makena[®], over the compounded CHC product prior to approval for reimbursement.

The FDA has announced “that it does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products.”

Due to prior success with CHC coupled with the narrow indications of Makena[®], West Virginia Medicaid will require documentation of medical necessity for Makena[®] over CHC.