Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	X	X	X	X	X	X

17-Hydroxyprogesterone Caproate Injection (non-Makena)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
17-Hydroxyprogesterone Caproate Injection

APPROVAL CRITERIA

Requests for 17-hydroxyprogesterone caproate injection may be approved when the following criteria are met:

I. Individual is a non-pregnant woman; **AND**
II. Individual is using for one of the following:
    A. The treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); **OR**
    B. Management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology (such as, submucous fibroids or uterine cancer); **OR**
    C. As a test for endogenous estrogen production and for the production of secretory endometrium and desquamation;

OR

III. Weekly injections between 16 and 36 weeks of gestation for the prevention of preterm delivery in high-risk pregnant individuals who meet the following criteria [off-label, Injectable Hydroxyprogesterone Caproate for Prevention of Preterm Birth CC (ING-CC-0053)]:
    A. Individual is between 16 weeks, 0 days and 36 weeks, 6 days of gestation; **AND**
    B. Therapy is initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation; **AND**
    C. A singleton pregnancy; **AND**
    D. Absence of preterm labor within the current pregnancy; **AND**
    E. A prior history of a preterm singleton delivery before 37 weeks gestation due to either of the following:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	NA	X	X	X	X	X	X

1. Spontaneous preterm labor; **OR**
2. Premature rupture of membranes.

17-hydroxyprogesterone caproate injection may not be approved when the above criteria are not met and for all other indications.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 7, 2019
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Determination That DELALUTIN (hydroxyprogesterone caproate) Injection, 125 Milligrams/Milliliter and 250 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness. Department of Health and Human Services, Food and Drug Administration. Docket No. FDA-2006-P-0089 (formerly Docket No. 2006P-0144). Available from: https://www.gpo.gov/fdsys/pkg/FR-2010-06-25/pdf/2010-15416.pdf. Accessed October 7, 2018.