Hydroxyprogesterone Caproate

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Hydroxyprogesterone Caproate

APPROVAL CRITERIA

Requests for hydroxyprogesterone caproate 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.

Requests for hydroxyprogesterone caproate may not be approved for the following:

I. For prevention of pre-term delivery or any subgroup of this population; **OR**
II. Hydroxyprogesterone caproate may not be approved when the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 10, 2023
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. American College of Obstetricians and Gynecologists (ACOG) Practice Advisory. Updated Clinical Guidance for the Use of Progesterone Supplementation for the Prevention of Recurrent Preterm Birth. Available at https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/04/updated-guidance-use-of-progesterone-supplementation-for-prevention-of-recurrent-preterm-birth. Accessed April 12, 2023

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DELALUTIN (hydroxyprogesterone caproate) Injection, 125 Milligrams/Milliliter and 250 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness.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 April 11, 2023.
6. Makena (hydroxyprogesterone caproate injection) Information. Department of Health and Human Services, Food and Drug Administration. Docket No. FDA-2020-N-2029. Available from: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information. Accessed: April 10, 2023.
7. FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena, Food and Drug Administration. Available from: https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena?utm_medium=email&utm_source=govdelivery. Accessed April 17, 2023
8. Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. *N Engl J Med*. 2003; 348:2379-85.
9. SMFM Special Statement: Response to the Food and Drug Administration's withdrawal of 17-alpha hydroxyprogesterone caproate. Available at https://www.smfm.org/publications/467-smfm-special-statement-response-to-the-food-and-drug-administrations-withdrawal-of-17-alpha-hydroxyprogesterone-caproate. Accessed April 12, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.