MedStar Family Choice

UPDATE to the MEDSTAR FAMILY CHOICE FORMULARY
Maryland Health Choice
May 2023 Pharmacy and Therapeutics Committee Meeting

Quarterly updates will be available on this Website and more frequently on Rx Navigator.

CHANGES BELOW WILL BECOME EFFECTIVE ON OR AROUND July 1, 2023

Please note effective July 1, 2023, MFC MD will reinstitute the 3-day override. Previously extended to 14-days due to the Public Health Emergency which ended May 11, 2023.

Additions:

- Kesimpta (ofatumumab)
- Clindamycin phosphate 1.2% and benzoyl peroxide 5% (45gm)
- Clindamycin phosphate 1% and benzoyl peroxide 5% (25 g, 35 g, 50 g)
- Chlorzoxazone 500mg
- Hyoscyamine Sulfate Tab Disintegrating 0.125

Additions with Prior Authorization: *

- Orserdu (elacestrant)
- Lunsumio (mosunetuzumab-axgb)
- Jaypirca (pirtobrutinib)
- Sunlenca (lenacapavir)
- Leqembi (lecanemab-irmb)

*Please see the PA Table on the MFC website for details of the requirements for approval and guidance on submission of clinical information

Removals:

- Danyelza
- Makena (see information related to Makena withdrawal from the market below)
- Lumoxiti

Addition of Prior Authorization:

- Drug Class Incretin Mimetic Agents (GLP-1): To prevent use of medications in this class for non-FDA approved indications (example: Ozempic and Mounjaro being prescribed solely for weight loss). This will include adding a PA to all the GLP -1 medicines on formulary.
    - Ozempic
    - Rybelsus

- Trulicity
- Victoza

Managed Drug Limitations & Step Therapy**

- Cough and Cold agents
  - All opioid (codeine/hydrocodone) agents are excluded for ages < 18yrs
  - Opioid and non-opioid are excluded for < 4 year of age.

*Details of the Prior Authorization Criteria are on this website in the Prior Authorization Table.
**Details of the Step Therapy Criteria are on this website in the Step Therapy Table.

Obstetrics and Gynecology Clinical Practice Update – Use of Makena (17-OHP)

FDA approval of Makena and all generic forms of 17-alpha hydroxyprogesterone caproate injection (17-OHP), was withdrawn on April 6, 2023, following a 2020 FDA recommendation for voluntary discontinuation of sales due to post-market studies that failed to verify clinical benefit. Available evidence does not show Makena is effective for the approved use.[1]

Makena was conditionally approved in 2011 to reduce the risk of preterm birth in women with a singleton pregnancy and history of a singleton, spontaneous preterm birth and was not indicated for use in women with multiple gestations or other risk factors for pre-term birth.[2]

The American College of Obstetricians and Gynecologists (ACOG) guidance regarding the use of progesterone for the prevention of preterm birth is included in ACOG Practice Bulletin No. 234, "Prediction and Prevention of Spontaneous Preterm Birth"[3] . Updated recommendations are:

- Vaginal progesterone has not been proven effective in the absence of a shortened cervix and should not be considered as an alternative to 17-OHPC. However, vaginal progesterone may be considered as a treatment option for patients with a history of preterm birth, singleton gestation, and a shortened cervix (≤ 25 mm length).
- Intramuscular 17-OHPC is not recommended for the primary prevention of preterm birth in patients with a history of spontaneous preterm birth.
- Dependent upon cervical length measurement, prior pregnancy history, and past treatment, a discussion of the range of interventions available to prevent a recurrent preterm birth should occur and a collaborative action plan should be developed.

Currently, no progesterone formulation carries an FDA-approved indication for prevention of preterm labor, all use is off-label. ACOG Clinical Guidance does not recommend vaginal progesterone administration in the absence of a shortened cervix, the demographic previously indicated for treatment with 17-OHP.

ACOG recommends the use of vaginal progesterone if the cervical length is ≤ 25 mm length when visualized during the 18- to 22-week gestation anatomy assessment and supports consideration of use versus cerclage with serial endovaginal ultrasound measurement of cervical length beginning at week 16 and repeated every 1 to 4 weeks until 24 weeks of gestation.[3]

In patients for whom the use of vaginal progesterone treatment is appropriate, there are two formulary products available for use:

- Crinone 8% vaginal gel

- Oral Progesterone 200 mg capsules (generic for Prometrium®) for intravaginal administration.

References:

1. https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena
2. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information
3. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/04/updated-guidance-use-of-progesterone-supplementation-for-prevention-of-recurrent-preterm-birth