Makena® (hydroxyprogesterone caproate)
(Intramuscular/Subcutaneous)

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I. Length of Authorization

Coverage will be provided for six months per singleton pregnancy and cannot be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Makena 250 mg/mL auto-injector 1.1 mL pre-filled syringe: 1 syringe weekly
- Makena 250 mg/mL single-dose 1 mL vial: 1 vial weekly
- Makena 250 mg/mL multi-dose 5 mL vial: 1 vial per 5 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

- 25 units every 7 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patients must have a contraindication or intolerance to the generic formulation of Makena® prior to consideration of the branded product; **AND**

Prevention of preterm birth (delivery at less than 37 weeks, 0 days gestation) †

- Patient is 16 years of age or older; **AND**
- Patient is currently pregnant with a singleton pregnancy; **AND**
- Patient must have history of a prior spontaneous singleton preterm birth due to spontaneous preterm labor or premature rupture of membranes; **AND**
- Confirmation that patient does not have any of the following contraindications:
    - Current or history of thrombosis or thromboembolic disorders; **OR**
    - Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions; **OR**
    - Undiagnosed abnormal vaginal bleeding unrelated to pregnancy; **OR**

- Cholestatic jaundice of pregnancy; **OR**
- Liver tumors, benign or malignant, or active liver disease; **OR**
- Uncontrolled hypertension; **AND**

- Therapy must be initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation and will continue through 36 weeks, 6 days gestation or delivery, whichever occurs first.

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration

Indication	Dose
Prevention of pre-term birth	▪ Treatment is initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation. ▪ Administration is continued once-weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first. Subcutaneous dose: ▪ 275 mg (1.1 mL), administered by a healthcare provider subcutaneously, once-weekly. Intramuscular dose: ▪ 250 mg (1 mL), administered by a healthcare provider intramuscularly, once-weekly.

VI. Billing Code/Availability Information

Jcode:

J1726 - Injection, hydroxyprogesterone caproate (Makena), 10 mg; 10 mg = 1 billable unit

NDC:

- Makena 250 mg/mL auto-injector 1.1 mL pre-filled syringe: 64011-0301-xx
- Makena* 250 mg/mL single-dose 1 mL vial: 64011-0247-xx
- Makena* 250 mg/mL multi-dose 5 mL vial: 64011-0243-xx

**Available generically from multiple manufacturers*

VII. References

1. Makena [package insert]. Waltham, MA; AMAG Pharmaceuticals, Inc; February 2018. Accessed January 2020.

2. American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins. Management of preterm labor. ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologist. Number 171. Obstet Gynecol. 2016 Oct;128(4):e155-64.
3. American College of Obstetricians and Gynecologists (ACOG). ACOG Committee Opinion No. 419, 2008. Use of progesterone to prevent preterm birth. Obstet Gynecol. 2008; 112(4):963-965.
4. O'Brien JM, Lewis DF. Prevention of preterm birth with vaginal progesterone or 17-alpha-hydroxyprogesterone caproate: a critical examination of efficacy and safety. Am J Obstet Gynecol. 2016 Jan;214(1):45-56.
5. Meis PJ, Klebanoff M, Thorn E, et al. Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate. N Engl J Med 2003; 348:2379-2385
DOI: 10.1056/NEJMoa035140

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
O09.212	Supervision of pregnancy with history of pre-term labor, second trimester
O09.213	Supervision of pregnancy with history of pre-term labor, third trimester
O09.219	Supervision of pregnancy with history of pre-term labor, unspecified trimester

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC