



Easy Choice Health Plan

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Makena® (17P)
Policy Number: HS-337

Original Effective Date: 8/24/2018

Revised Date(s): 11/1/2018

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

In the United States, preterm birth complicates 1 in 8 deliveries. Preterm babies account for over 85 percent of all perinatal morbidity and mortality.¹ Ideally, in a healthy pregnancy, a baby is carried to full term (39-40 weeks gestation) and has plenty of time to grow and develop. Preterm babies are those born before 37 weeks of gestation. Any woman can be at risk for having a preterm delivery, but those who have a preterm delivery in the past are at higher risk for having another preterm baby. Common risk factors for preterm births are multiple gestation pregnancies, problems with the uterus or cervix, short time between pregnancies and certain infections and sexually transmitted diseases. Women of African American heritage, those with high blood pressure or diabetes, those who are overweight and those who drink alcohol, smoke or use illicit drugs are also at higher risk for preterm delivery.²

Progesterone has been found to contribute to maintaining pregnancy in several ways. Corpus luteum progesterone

production is critical for pregnancy maintenance until the placenta takes over this function at 7 to 9 weeks of gestation. Also progesterone maintains uterine dormancy or inactivity during the latter half of pregnancy. Finally, progesterone prevents apoptosis in fetal membrane explants under both basal and pro-inflammatory conditions and therefore may protect the membranes from preterm prelabor rupture and, in turn, preterm birth.¹

Progesterone supplementation has been shown to reduce the rate of preterm birth in women with a singleton pregnancy. It has not, however, been found effective in woman with multiple gestations (twins, triplets, etc.).¹

Makena® (hydroxyprogesterone caproate injection) is a progestin medication indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. It was originally approved for use in the United States in 1956. Makena® is only intended for use in women with singleton pregnancies and is not for use in women with multiple gestations.³

Makena® can be administered subcutaneously or intramuscularly. Treatment should begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation, but may begin as late as 26 weeks, 6 days of gestation. Administration should be continued once weekly until week 37 of gestation or delivery, whichever comes first. Intramuscular administration can be done by a healthcare provider in their office or in the home.^{3,4} The most commonly reported adverse reactions with Makena® were injection site reactions, swelling, pruritus and urticaria.³

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

Exclusions

Administration of Makena® (17P) in a home health setting by a home health nurse is **not considered medically necessary and not a covered benefit** when any of the following apply:

1. Member has a history of any of the following contraindications:
 - A. Thrombosis or thromboembolic disorders; **OR**
 - B. Known or suspected breast cancer or history of these conditions; **OR**
 - C. Undiagnosed abnormal vaginal bleeding unrelated to pregnancy; **OR**
 - D. Cholestatic jaundice of pregnancy; **OR**
 - E. Liver tumors (benign or malignant) or active liver disease; **OR**
 - F. Uncontrolled hypertension
2. Makena® (17P) is not intended for use in women with multiple gestations.

Coverage

Administration of Makena® (17P) in a home health setting by a home health nurse is **considered medically necessary and a covered benefit** when any of the following apply:

1. Prescriber is one of the following:
 - A. the Member's obstetrician; **OR**
 - B. Nebraska members only – The member's primary care physician,**AND,**
2. Member is between 16 and 50 years of age; **AND,**
3. Medication must be initiated between week 16, 0 days and 26 weeks, 6 days of gestation with the coverage duration being up to 21 weeks; **AND,**
4. Maximum dose is 250 mg weekly; **AND,**
5. Member must have a statement of need (medical necessity) for preterm delivery prophylaxis in females with a singleton pregnancy who have a history of singleton spontaneous preterm birth; **AND,**
6. Medication must be continued weekly until week 37 of gestation or delivery, whichever comes first

CODING

Covered CPT Codes – None.

Covered HCPCS Codes

- J1726** Injection, hydroxyprogesterone caproate (Makena), 10 mg
- J1729** Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg
- J2675** Injection, progesterone, per 50 mg

Covered ICD-10 Codes

- O09.211** Supervision of pregnancy with history of pre-term labor, first trimester
- 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
- O20.0** Threatened abortion
- O20.8** Other hemorrhage in early pregnancy
- O20.9** Hemorrhage in early pregnancy, unspecified
- O47.00** False labor before 37 completed weeks of gestation, unspecified trimester
- O47.02** False labor before 37 completed weeks of gestation, second trimester
- O47.03** False labor before 37 completed weeks of gestation, third trimester
- O47.1** False labor at or after 37 completed weeks of gestation
- O47.9** False labor, unspecified
- O60.00** Preterm labor without delivery, unspecified trimester
- O60.02** Preterm labor without delivery, second trimester
- O60.03** Preterm labor without delivery, third trimester
- O60.10X0** Preterm labor with preterm delivery, unspecified trimester, not applicable or unspecified
- O60.12X0** Preterm labor second trimester with preterm delivery second trimester, not applicable or unspecified
- O60.13X0** Preterm labor second trimester with preterm delivery third trimester, not applicable or unspecified
- O60.14X0** Preterm labor third trimester with preterm delivery third trimester, not applicable or unspecified
- O60.20X0** Term delivery with preterm labor, unspecified trimester, not applicable or unspecified
- O60.22X0** Term delivery with preterm labor, second trimester, not applicable or unspecified
- O60.23X0** Term delivery with preterm labor, third trimester, not applicable or unspecified
- Z3A.16** 16 weeks gestation of pregnancy
- Z3A.17** 17 weeks gestation of pregnancy
- Z3A.18** 18 weeks gestation of pregnancy
- Z3A.19** 19 weeks gestation of pregnancy
- Z3A.20** 20 weeks gestation of pregnancy
- Z3A.21** 21 weeks gestation of pregnancy
- Z3A.22** 22 weeks gestation of pregnancy
- Z3A.23** 23 weeks gestation of pregnancy
- Z3A.24** 24 weeks gestation of pregnancy
- Z3A.25** 25 weeks gestation of pregnancy
- Z3A.26** 26 weeks gestation of pregnancy
- Z3A.27** 27 weeks gestation of pregnancy
- Z3A.28** 28 weeks gestation of pregnancy
- Z3A.29** 29 weeks gestation of pregnancy
- Z3A.30** 30 weeks gestation of pregnancy
- Z3A.31** 31 weeks gestation of pregnancy
- Z3A.32** 32 weeks gestation of pregnancy
- Z3A.33** 33 weeks gestation of pregnancy
- Z3A.35** 35 weeks gestation of pregnancy
- Z3A.36** 36 weeks gestation of pregnancy
- Z87.51** Personal history of pre-term labor

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Norwitz, E.R. Progesterone supplementation to reduce the risk of spontaneous preterm birth. UpToDate Website www.uptodate.com. Published July 17, 2018. Accessed August 10, 2018.
2. Understanding preterm birth. AMAG Corporate Website <http://www.makena.com/understanding-preterm-birth>. Published February, 2018. Accessed August 10, 2018.
3. Label: Makena - hydroxyprogesterone caproate injection. Daily Med Website <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a1998c1d-8337-4f00-8dcb-af3b54d39b77>. Published Feb 26, 2018. Accessed August 10, 2018.
4. Reducing risk with Makena. AMAG Corporate Website <http://www.makena.com/reducing-preterm-birth-risk-with-makena>. Published February 2018. Accessed August 10, 2018.
5. 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 43, May, 2003. Obstet Gynecol, 101, 1039-1047.
6. Society of Obstetricians and Gynecologists of Canada. The Use of Progesterone for Prevention of Preterm Labor, Journal of Obstetrics and Gynecology of Canada, 202, 2008.
7. ACOG Guidelines - Preventing Preterm Birth: <https://www.acog.org/About-ACOG/ACOG-Districts/District-II/Preventing-Preterm-Birth-For-Providers>. Accessed August 3, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
11/1/2018	<ul style="list-style-type: none"> • Approved by MPC. Added NE specific criteria for prescribing provider.
8/24/2018	<ul style="list-style-type: none"> • Approved by MPC. New.