Makena PA Criteria

1. Is the patient being treated for an OHP funded condition?
   a. If Yes, go to question #2
   b. If No, review documentation for relevant comorbid conditions that are funded by OHP. If there are relevant comorbid conditions, move to question #2. If there are no relevant comorbid conditions, Cat. 1 denial.
      Cat 1: Not a covered benefit. Provider submitted diagnosis code is not for an OHP funded condition. No relevant comorbid conditions found in the provider submitted documentation.

2. Is the patient between 16 weeks and 0 days and 36 weeks 6 days gestation with a singleton pregnancy?
   a. If Yes, go to question #3
   b. If No, Cat. 3 denial
      Cat 3: Makena is indicated for prevention of preterm birth for pregnant females between 16 weeks 0 days until 37 weeks gestation or delivery whichever comes first.

3. Has the patient had a prior history of preterm delivery before 37 weeks gestation (spontaneous preterm singleton birth)?
   a. If Yes, go to question #4
   b. If No, Cat. 5 denial
      Cat 5: Safety and efficacy have been demonstrated only in women with a prior spontaneous singleton preterm birth. Use is not intended for women with multiple gestations or other risk factors for preterm birth.

4. Is treatment being initiated at 16 weeks, 0 days and to 20 weeks, 6 days of gestation?
   a. If Yes, approve through week 37 of gestation or delivery, whichever occurs first (no more than 20 doses).
   b. If No, Cat. 3 denial
      Cat 3: Makena is FDA approved for therapy to being between 16 weeks 0 days and 20 weeks 6 days of gestation. Documentation indicates that patient is outside of this prescribing range.