Non-formulary Freestyle Libre will be covered when the following criteria are met:

1. Type 1 diabetes mellitus -OR-

2. Type 2 diabetes mellitus AND insulinopenia;
   a. Insulinopenia is defined as a fasting C-peptide level of less than or equal to 0.88 ng/mL with a concurrent glucose of 70-225 mg/dL
   b. In those with renal insufficiency with a creatinine clearance less than or equal to 50 ml/minute, insulinopenia is defined as a C-peptide level of less than or equal to 1.6 ng/mL with a concurrent glucose of 70-225 mg/dL
   -AND-

3. Patient is on either insulin pump therapy or on multiple (3 or more) daily injection (MDI) regimen (basal insulin plus bolus insulin)
   -AND-

4. Patient meets at least one of the following:
   a. Diagnosed hypoglycemia unawareness; OR
   b. Refractory nocturnal hypoglycemia with at least 2 episodes of nocturnal hypoglycemia less than 50 mg/dL in past month; OR
   c. Refractory daytime hypoglycemia with at least 2 episodes of hypoglycemia less than 50 mg/dL in past week; OR
   d. Any severe hypoglycemia event (defined as needing assistance of someone else during hypoglycemia or hypoglycemia associated with seizures or loss of consciousness

Comments
1. Members who are currently using CGMS and new to Kaiser coverage are exempt from the requirement to meet criteria 3. New members will receive coverage of ongoing CGMS supplies, as long as they are compliant with CGMS therapy.
2. To be effective, CGMS should be used regularly. Compliance is defined by at least 5 days per week of use or 20 days of use per month.
3. Regularly (at each visit with the treating diabetologist) CGMS should be downloaded.
4. Endocrinology uses the following statement in the patient literature. “The criteria here apply to members whose insurance is Kaiser Permanente or Senior Advantage Medicare. Other insurance carriers (such as Medicaid and non-Senior Advantage Medicare) determine their own criteria. If you have a non-Kaiser insurance carrier (such as Medicaid and non-Senior Advantage Medicare), please contact your insurance carrier for more information regarding coverage rules.”