Generic Name: N/A

Applicable Drugs (if therapeutic class):

Byetta® (exenatide), Bydureon BCise® (exenatide), Mounjaro™ (tirzepatide), Ozempic® (semaglutide), Rybelsus® (semaglutide), Trulicity® (dulaglutide), Victoza® (liraglutide)

Date of Origin: 8/29/2022

Date Last Reviewed / Revised: 3/12/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when certain criteria are met. Criteria differs between formularies, refer to Other Criteria within this policy for specific requirements.

I. The following prior authorization criteria only apply in the event where an electronic edit is unable to confirm a type 2 diabetes indication or the incretin mimetic is non-preferred:

   A. Medical record documentation of type 2 diabetes mellitus diagnosis and meets 1 or 2:

      1. Unequivocal hyperglycemia confirmed with at least one of the following diagnostic lab requirements:

         a) HbA1c greater or equal to 6.5% at baseline.

         b) FPG greater or equal to 126 mg/dL. Fasting is defined as no caloric intake for at least 8 hours.

         c) 2-h PG greater or equal to 200mg/dL during OGTT. Test should be described by the WHO, using glucose load containing the equivalent of 75 g anhydrous glucose.

         d) Classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose greater or equal to 200 mg/dL. Random is any time of the day without regard to time since previous meal.

         e) In the absence of unequivocal hyperglycemia (e.g., hyperglycemic crisis), diagnosis requires two abnormal test results obtained at the same time (e.g. A1C and FPG) or at two different time points.

      2. For patients receiving ongoing treatment for type 2 diabetes mellitus and were diagnosed > 2 years, chart notes confirm type 2 diabetes mellitus diagnosis and assessments within the past year.

II. Patient meets one of the following criteria A or B:

   A. Patient is antidiabetic medication-naïve with HbA1c ≥ 8.5% (drawn within past 3 months), and the incretin mimetic will be initiated alongside metformin.

B. Patient is using Metformin/metformin combination at optimized dose or has a contraindication to metformin/metformin combination and meets one of the following criteria 1 - 3:

1. Documented uncontrolled hyperglycemia as evidenced by HbA1c greater or equal to 6.5% despite adherence. Trial must be a duration of at least 60 days in the last 180 days or documentation of intolerance to maximally tolerated dose.
2. Documented established cardiovascular disease and request is for Ozempic, Trulicity, or Victoza.
3. Documented age of at least 55 years and ≥ 2 additional cardiovascular risk factors (including obesity, hypertension, smoking, dyslipidemia, or albuminuria) and the request is for Trulicity.

III. Minimum age requirement A or B:

A. 18 years: Byetta, Bydureon, Mounjaro, Ozempic, Rybelsus.

B. 10 years and older: Trulicity and Victoza.

IV. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to preferred product(s).

EXCLUSION CRITERIA

- Personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2.
- Concurrent use of DPP4-Inhibitor.

OTHER CRITERIA

- Ventegra Premium Plus formulary
  - Preferred agents must meet prior authorization criteria under I, III, and IV
  - Non-preferred agents must meet prior authorization criteria I through IV
- Ventegra Premium formulary
  - Prior authorization criteria under I through IV must be met.
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QUANTITY / DAYS SUPPLY RESTRICTIONS

- Bydureon: 4 autoinjector pens per 28 days.
- Byetta: 1 prefilled pen per 30 days.
- Mounjaro: 4 pen injectors per 28 days.

- Rybelsus: 30 tablets per 30 days.
- Ozempic: 1 pen injector per 28 days.
- Trulicity: 4 pen per 28 days.
- Victoza: 3 pen injectors per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

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13. Dahl, Dominik et al. "Effect of subcutaneous tirzepatide vs placebo added to titrated insulin glargine on glycemic control in patients with type 2 diabetes." JAMA327(6)(2022): 534-545. doi.org/10.1001/jama.2022.0078.
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15. Lin GA, Brouwer E, Nikitin D et al. Tirzepatide for type 2 diabetes; final report. Institute for Clinical and Economic Review, February 15, 2022. https://icer.org/assessment/diabetes-type-2-2022/#timeline