Subject: GLP-1 Agonist Rybelsus PA with Limit Policy 3318-C UDR 05-2024

Drug
GLUCAGON-LIKE PEPTIDE 1 (GLP-1) RECEPTOR AGONIST
RYBELSUS *(semaglutide)*

Policy:

FDA-APPROVED INDICATIONS
Rybelsus is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use
- Rybelsus has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Rybelsus is not indicated for use in patients with type 1 diabetes mellitus.

COVERAGE CRITERIA

Type 2 Diabetes Mellitus
Authorization may be granted when the patient has a diagnosis of type 2 diabetes mellitus when the following criteria are met:
- The patient has NOT been receiving a stable maintenance dose of a GLP-1 (glucagon-like peptide 1) Agonist for at least 3 months [Note: Examples of GLP-1 Agonists are Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza] and ONE of the following criteria are met
    - The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to metformin
    - The patient requires combination therapy AND has an A1C of 7.5 percent or greater

CONTINUATION OF THERAPY

Type 2 Diabetes Mellitus
Authorization may be granted when the patient has a diagnosis of type 2 diabetes mellitus when the following criteria are met:
- The patient has been receiving a stable maintenance dose of a GLP-1 (glucagon-like peptide 1) Agonist for at least 3 months [Note: Examples of GLP-1 Agonists are Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza] and the following criteria is met:
    - The patient has demonstrated a reduction in A1C since starting GLP-1 (glucagon-like peptide 1) Agonist therapy

QUANTITY LIMITS APPLY
30 tablets per 25 days* or 90 tablets per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for an 90-day fill period to allow time for refill processing.*

DURATION OF APPROVAL
- 3318-C: 36 months

Place of Service:

Outpatient

The above policy is based on the following references:

1. Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed March 11, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/11/2024).

4. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. Endocr Pract. 2022;28(10):923-1049.
5. Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2022;45(11):2753-2786.
6. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – 2024. Diabetes Care. 2024;47(Suppl. 1):S1-S322.
7. Samson SL, Vellank P, Blonde L, et. Al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. Endocr Pract. 2023; 29: 305-340.

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