BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/21/19
LAST REVIEW DATE: 11/21/19
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ARCHIVE DATE:

RYBELSUS® (semaglutide) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

RYBELSUS® (semaglutide) oral tablet

Criteria:

- **Criteria for initial therapy:** Rybelsus (semaglutide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in patient's diagnosis or is in consultation with an Endocrinologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of type 2 diabetes mellitus to be used as an adjunct to diet and exercise to improve glycemic control
  4. Individual has failure, contraindication or intolerance to **THREE** of the following preferred step therapy agents:
     - Bydureon (exenatide)
     - Byetta (exenatide)
     - Tanzeum (albiglutide)
     - Trulicity (delaglutide)
     - Victoza (liraglutide)
  5. There are **NO** contraindications
     - Contraindications include:
       - Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2
       - Known hypersensitivity to semaglutide or any of the components in the product

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rybelsus (semaglutide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in patient's diagnosis or is in consultation with an Endocrinologist
  2. Individual's condition responded while on therapy
     - Response is defined as:
       - No evidence of disease progression
       - Achieved and maintains a reduction in HbA1C of at least 1.0%
  3. Individual has been adherent with the medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section

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- Significant adverse effect such as:
  - Pancreatitis
  - Thyroid cancer
  - Multiple Endocrine Neoplasia type 2

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Rybelsus (semaglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It is not recommended as first-line therapy for patients inadequately controlled on diet and exercise and it is not indicated for use in patients with type 1 diabetes mellitus or treatment of diabetic ketoacidosis. It has not been studied in patients with a history of pancreatitis. Rybelsus (semaglutide) is the first oral GLP-1 receptor agonist. Semaglutide is also available as injectable Ozempic. Semaglutide is co-formulated with salcaprozate sodium which facilitates the absorption of semaglutide after oral administration. The absorption of semaglutide predominantly occurs in the stomach.

Semaglutide reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependent manner. Thus, when blood glucose is high, insulin secretion is stimulated and glucagon secretion is inhibited. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase. Semaglutide reduces fasting and postprandial glucose concentrations. It also lowers the fasting and postprandial glucagon concentrations. Semaglutide increases first- and second-phase insulin secretion.

Resources:

Rybelsus (semaglutide) product information accessed 10-11-19 at DailyMed