



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors, DPP-4 Inhibitor Combination Drugs, Cycloset (bromocriptine)

Policy # 00306

Original Effective Date: 05/22/2013

Current Effective Date: 05/21/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider dipeptidyl peptidase-4 (DPP-4) inhibitors including, but not limited to Januvia^{®†} (sitagliptin), Onglyza^{®†} (saxagliptin), Tradjenta^{®†} (linagliptin), and Nesina^{®†} (alogliptin) OR dipeptidyl peptidase-4 inhibitor combination drugs including, but not limited to Janumet^{®†} (sitagliptin/metformin), Juvisync^{®†} (sitagliptin/simvastatin), Kombiglyze^{®†} (saxagliptin/metformin), Kazano^{®†} (alogliptin/metformin), and Oseni^{®†} (alogliptin/pioglitazone) OR Cycloset^{®†} (bromocriptine) to be **eligible for coverage** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for the following drugs when their respective patient selection criteria are met:

- For dipeptidyl peptidase-4 (DPP-4) inhibitors (non-combo), dipeptidyl peptidase-4 (DPP-4) inhibitor combination drugs, or Cycloset (bromocriptine): Patient has tried a metformin or metformin-containing combination product (brand or generic); OR
- For dipeptidyl peptidase-4 (DPP-4) inhibitors (non-combo), dipeptidyl peptidase-4 (DPP-4) inhibitor combination drugs, or Cycloset (bromocriptine): There is clinical evidence or patient history that suggests metformin products will be ineffective or cause an adverse reaction to the patient; OR
- For dipeptidyl peptidase-4 (DPP-4) inhibitors (non-combo) or Cycloset (bromocriptine): Patient is initiating dual therapy with metformin OR patient has ONE of the following conditions:
 - Hepatic impairment; OR
 - Alcohol dependence; OR
 - Renal insufficiency or renal disease; OR
 - Cardiomyopathy, heart failure, unstable, angina, or a myocardial infarction; OR
 - A condition that could potentially increase the risk of hypoperfusion, hypoxemia, or dehydration; OR
 - Chronic metabolic acidosis

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of dipeptidyl peptidase-4 (DPP-4) inhibitors, dipeptidyl peptidase-4 (DPP-4) inhibitor combination drugs, or Cycloset (bromocriptine) when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.**

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Background/Overview

Dipeptidyl peptidase-4 inhibitors and DPP-4 inhibitor combination drugs are approved for patients with Type 2 Diabetes Mellitus. Cycloset (bromocriptine) is also approved for patients with Type 2 Diabetes Mellitus as an adjunct to diet and exercise.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests metformin products will be ineffective or cause an adverse reaction to the patient. This policy also takes into consideration other situations in which using metformin as a first-line treatment is not appropriate. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a DPP-4 inhibitor, DPP-4 inhibitor combination drug, or Cycloset (bromocriptine) over the available brand or generic metformin products.

References

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Policy History

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Current Effective Date: 05/21/2014

05/02/2013 Medical Policy Committee review

05/22/2013 Medical Policy Implementation Committee approval. New policy.

05/01/2014 Medical Policy Committee review

05/21/2014 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 05/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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