

Policies Repository



Policy Title Repaglinide and Metformin hydrochloride (PrandiMet™)

Policy Number FS.CLIN.65

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Repaglinide and Metformin hydrochloride (PrandiMet™)** is a meglitinide and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a meglitinide and metformin HCl or who have inadequate glycemic control on a meglitinide alone or metformin HCl alone.

The use of Repaglinide and Metformin hydrochloride (PrandiMet™) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Repaglinide and Metformin hydrochloride (PrandiMet™)** tablets contain two oral antihyperglycemic drugs used in the management of type 2 diabetes: repaglinide and metformin HCl. The concomitant use of repaglinide and metformin HCl has been previously approved based on clinical trials in patients with type 2 diabetes inadequately controlled on exercise, diet, and metformin HCl alone.

Repaglinide lowers blood glucose levels by stimulating the release of insulin from the pancreas. This action is dependent upon functioning beta (β) cells in the pancreatic islets. Repaglinide closes ATP-dependent potassium channels in the β-cell membrane by binding at characterizable sites. This potassium channel blockade depolarizes the β-cell, which leads to an opening of calcium channels. The resulting increased calcium influx induces insulin secretion. The ion channel mechanism is highly tissue selective with low affinity for heart and skeletal muscle. Metformin is an anti-hyperglycemic agent, which improves glucose tolerance in patients with type 2 diabetes by lowering both the basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and day-long plasma insulin response may actually decrease.

Policy Guideline Inclusion **Repaglinide and Metformin hydrochloride (PrandiMet™)** is approved when **all** of the following inclusion criteria are met:

- Documentation of diagnosis of type 2 diabetes mellitus
- Documentation of non-compliance with the concurrent use of Prandin (repaglinide) and a

metformin-containing product

- Documentation of a minimum 30 day trial of concurrent use of Prandin (repaglinide) and a metformin-containing product

Policy Guideline Exclusion

Repaglinide and Metformin hydrochloride (PrandiMet™) is denied when **any** of the following exclusion criteria are found:

- No documentation of diagnosis of type 2 diabetes mellitus
- No documentation of non-compliance with the concurrent use of Prandin (repaglinide) and a metformin-containing product
- No documentation of a minimum 30 day trial of concurrent use of Prandin (repaglinide) and a metformin-containing product

Policy List of Applicable Drugs

| Brand Name | Generic Name |
|------------|---|
| PrandiMet | Repaglinide and Metformin hydrochloride |

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

PrandiMet™ (repaglinide and metformin HCl). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed February 15, 2009.

PrandiMet™ (repaglinide and metformin HCl). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed February 15, 2009.

PrandiMet™ (repaglinide and metformin HCl). Princeton, New Jersey; Novo Nordisk A/S: June 2008.

Policy Link to Related Policies

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