

## Policies Repository



**Policy Title** Oral Diabetic Agents

**Policy Number** FS.CLIN.10

***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**

Sitagliptin (Januvia™) is indicated for the treatment of type 2 diabetes mellitus as monotherapy or in combination with metformin or a thiazolidinedione when a single agent does not provide adequate glycemic control.

Metformin extended-release (ER) (Glumetza™) is indicated for the treatment of type 2 diabetes mellitus.

Sitagliptin/metformin (Janumet™) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on sitagliptin (Januvia™) or metformin alone or who are already being treated with sitagliptin (Januvia™) and metformin concomitantly.

The use of sitagliptin (Januvia™), metformin ER (Glumetza™), and sitagliptin/metformin (Janumet™) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

**Policy Description**

Sitagliptin (Januvia™) is a dipeptidyl peptidase-4 (DPP-4) enzyme inhibitor that exerts its activity in individuals with type 2 diabetes mellitus by protecting the endogenous incretin hormones and enhancing their actions. Glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) are incretin hormones that are released in response to food intake to maintain glucose homeostasis. However, GIP and GLP-1 are metabolized rapidly by the DPP-4 enzyme, resulting in the loss of insulinotropic effects. Sitagliptin (Januvia™) inhibits the degradation of incretin hormones by DPP-4 and enhances the function of GIP and GLP-1 to increase insulin release and to decrease glucagon circulation levels in a glucose-dependent manner.

Metformin extended-release (ER) (Glumetza™) is an oral antihyperglycemic drug used in the management of type 2 diabetes mellitus. Its pharmacologic mechanism of action is similar to the mechanism of action of other formulations of metformin: it decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by

increasing peripheral glucose uptake and utilization.

Sitagliptin/metformin (Janumet™) is a combination of the above medications. As such, the pharmacological description is explained above.

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### Policy Guideline Inclusion

#### SITAGLIPTIN (JANUVIA™)

Sitagliptin (Januvia™) is approved when **all** of the following inclusion criteria are met:

- Documentation of type 2 diabetes mellitus
- Documentation of the trial and failure of or contraindication to a metformin-containing product
- Documentation of the trial and failure of one of the following:
  - A thiazolidinedione
  - A sulfonylurea

#### METFORMIN ER (GLUMETZA™)

Metformin ER (Glumetza™) is approved when **all** of the following inclusion criteria are met:

- Documentation of type 2 diabetes mellitus
- Documentation of the trial and failure of or intolerance/allergy/contraindication to either metformin IR- or metformin ER-containing products

#### SITAGLIPTIN/METFORMIN (JANUMET™)

Sitagliptin/metformin (Janumet™) is approved when there is documentation of type 2 diabetes mellitus and when **one** of the following inclusion criteria is met:

- Documentation of current concomitant therapy with sitagliptin and metformin
- Documentation of current therapy with metformin and the trial and failure of one of the following:
  - A thiazolidinedione
  - A sulfonylurea
- Documentation of current therapy with metformin and a contraindication to both of the following:
  - A thiazolidinedione
  - A sulfonylurea

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### Policy Guideline Exclusion

#### SITAGLIPTIN (JANUVIA™)

Sitagliptin (Januvia™) is denied when **any** of the following exclusion criteria are present:

- No documentation of type 2 diabetes mellitus
- No documentation of the trial and failure of or contraindication to a metformin-containing product
- No documentation of the trial and failure of one of the following:
  - A thiazolidinedione
  - A sulfonylurea

#### METFORMIN ER (GLUMETZA™)

Metformin ER (Glumetza™) is denied when **any** of the following exclusion criteria are present:

- No documentation of type 2 diabetes mellitus
- No documentation of the trial and failure of or intolerance/allergy/contraindication to either metformin IR- or metformin ER-containing products

#### SITAGLIPTIN/METFORMIN (JANUMET™)

Sitagliptin/metformin (Janumet™) is denied when there is no documentation of type 2 diabetes mellitus and when **all** of the following exclusion criteria are present:

- No documentation of current concomitant therapy with sitagliptin and metformin
- No documentation of current therapy with metformin and the trial and failure of one of the following:
  - A thiazolidinedione
  - A sulfonylurea
- No documentation of current therapy with metformin and a contraindication to both of the following:
  - A thiazolidinedione
  - A sulfonylurea

#### Policy List of Applicable Drugs

Brand Name	Generic Name
Januvia	Sitagliptin
Janumet	Sitagliptin/metformin
Glumetza	Metformin ER

#### Dosing and Administration

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

#### Policy References

Glumetza™ (metformin hydrochloride extended release tablets) [package insert]. Menlo Park, CA: Depomed, Inc.; 2007. Also available online at: [http://www.glumetzaxr.com/pdf/current\\_PI\\_PW2.pdf](http://www.glumetzaxr.com/pdf/current_PI_PW2.pdf). Accessed August 4, 2008.

Merck. Januvia™ (sitagliptin) tablets. [Januvia Web site]. Available at: <http://www.januvia.com>. Accessed August 4, 2008.

Micromedex. Glumetza™ (metformin extended release tablets). [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed August 4, 2008.

Micromedex. Janumet™ (sitagliptin/metformin). [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed August 4, 2008.

Micromedex. Januvia™ (sitagliptin). [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed August 4, 2008.

#### Policy Link to Related Policies

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