Progressive Medication Program for 
Glumetza® (metformin extended release tablets) 

| Origination: 08/29/12 | Revised: 07/31/14 | Annual Review: 11/19/14 |

**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Reference Statement**

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

**Medication Summary**

- Metformin is an oral biguanide antidiabetic agent. Its actions differ, but complement sulfonylurea and other antidiabetic therapies. There are several formulations of metformin, including regular release metformin hydrochloride tablets, metformin hydrochloride oral solution, metformin extended release tablets. There are three different extended-release tablet versions that differ in their pharmacokinetic profiles, including generic Glucophage XR, generic Fortamet and Glumetza®.

- Generic metformin XR tablets (Glucophage XR) uses a dual hydrophilic polymer system to slowly diffuse metformin through a gel matrix. Peak plasma concentrations occur at approximately 7 hours. Food increases absorption by approximately 50% but the concentration maximum (Cmax) remains unchanged.

- Generic metformin extended-release tablets (Fortamet) use single composition osmotic technology to release metformin at a constant rate from an osmotically active tablet core surrounded by a semi-permeable membrane. Bioavailability of Fortamet 2000mg once daily in the evening is similar to the same total daily dose administered as regular-release tablets 1000mg twice daily. Food increases absorption by approximately 60% and the Cmax is increased 30%.

- Glumetza® (metformin extended-release tablets) uses gastric-retentive technology to deliver metformin to the upper GI tract to enhance absorption over an extended period of time. Glumetza® must be given directly after a meal to maximize therapeutic benefit. Once daily Glumetza® 1000mg provides equivalent systemic exposure (AUC) and up to 35% higher Cmax concentrations when compared to 500mg twice daily regular-release tablets. Low fat and high fat meals increase systemic exposure by 38% and 73% respectively relative to fasting. Cmax is not affected by meals.
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Coverage Guidelines

- Member must be eligible for benefit coverage within the specified date(s) of service. Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Members with any of the following conditions: diabetic ketoacidosis, metabolic acidosis, or renal failure.
- Members with radiographic contrast administration.

Procedure:

1.0 Request for initial therapy with Glumetza® for diabetes requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying the following:

1.1 Member is new Member to AvMed (eligibility within the past 120 days) and has been on targeted medication prior to joining AvMed (evidenced by progress notes from prescriber indicating use or documented previous fill history with pharmacy);

OR

1.1 Member has tried and failed an adequate trial (at least 2 consecutive months) of metformin hcl er tablets (generic Glucophage XR) or Member has had intolerable side effects to metformin hcl er tablets (generic Glucophage XR);

1.2 If criteria are approved, Glumetza® may be approved for one (1) month with a quantity limit of 60 tablets for 30 days:

1.2.1 Refills should continue to process every month thereafter.

References:


Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed’s benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions based on the Member’s benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed’s Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.