Clinical Policy: Metformin ER (Glumetza)

Reference Number: PA.CP.PMN.72
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
Metformin ER (Glumetza®) is an oral biguanide antidiabetic agent.

FDA approved indication

- Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
  Limitations of use: Glumetza should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria**

It is the policy of Pennsylvania Health and Wellness® that Glumetza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Type 2 Diabetes Mellitus (must meet all)**:**

1. Diagnosis of type 2 diabetes mellitus;
2. Member experienced clinically significant adverse effects to immediate release metformin or has contraindication(s) to its excipients;
3. Member experienced clinically significant adverse effects to metformin ER tablets (Glucophage® XR, Fortamet®) or has contraindication(s) to its excipients;
4. If request is for brand Glumetza, member has experienced clinically significant adverse effects to generic Glumetza or has contraindication(s) to its excipients;
5. Request does not exceed 2000 mg/day

Approval duration: 12 months

B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Type 2 Diabetes Mellitus (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or Continuity of Care policy applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2000 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Type 1 diabetes mellitus;
B. Diabetic ketoacidosis.
C. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
eGFR: estimated glomerular filtration rate

V. Dosage and Administration

- The starting dose of Glumetza in patients who are not currently taking metformin is 500 mg orally, once daily with the evening meal. Increase the dose in 500 mg increments every 1-2 weeks if a higher dose of Glumetza is needed and there are no gastrointestinal adverse reactions.
- The dosage of Glumetza must be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended daily dose of 2000 mg.
- Prior to initiation, assess renal function with eGFR.
- Glumetza may need to be discontinued at time of, or prior to, iodinated contrast imaging procedures.
- Glumetza tablets must be swallowed whole and never split, crushed or chewed.

VI. Product Availability

Glumetza is supplied as extended release tablets in the following strengths: 500 mg and 1000 mg.

VII. References

1. Glumetza Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; April 2017. Available at: https://shared.salix.com/shared/pi/glumetza-pi.pdf. Accessed January 17, 2018.
1.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed January 17, 2018.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added that members requesting brand Glumetza must have contraindication or intolerance to generic Glumetza; removed age limit and contraindication since other formulations of metformin are available freely on PDL without such restrictions; increased initial approval duration from 3 months to 12 months; references reviewed and updated.	02.27.18	