Metformin

Description
Fortamet (extended-release metformin osmotic), Glumetza* (extended-release metformin), Riomet (metformin oral solution), Metformin ER (modified & osmotic)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

Background
Metformin is an oral antidiabetic medication used to improve glycemic control in adults with type 2 diabetes mellitus. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, and loss of limbs. Proper control of diabetes may also lessen the risk of a heart attack or stroke. Metformin works by helping to restore the body’s proper response to the insulin it naturally produces. It also decreases the amount of sugar that the liver makes and that the stomach/intestines absorb (1-3).

Regulatory status
FDA Approved Indications: Metformin is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (1-3).

Limitations of Use:
Metformin is not used for the treatment of type 1 diabetes or ketoacidosis (1-3).

Metformin carries a boxed warning regarding the risk of lactic acidosis, which may be fatal. Increased risk is associated with hypotensive states such as acute congestive heart failure and
Acute myocardial infarction. Metformin is contraindicated in patients with renal impairment, metabolic acidosis or hypersensitivity to metformin hydrochloride. Before initiating therapy with Metformin, evaluate the patient’s renal function (1-3).

Patients should be warned against excessive alcohol intake while taking Metformin (1-3).

The safety and effectiveness of Glumetza and Fortamet in pediatric patients less than 18 years of age have not been established (2). The safety and effectiveness of Riomet in pediatric patients less than 10 years of age have not been established (1, 3).

Related policies
SGLT2 Inhibitors

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Metformin may be considered medically necessary in patients with type 2 diabetes mellitus and if the conditions indicated below are met.

Metformin is considered investigational for all other indications.

Prior-Approval Requirements

Age

Glumetza and Fortamet only: 18 years of age or older

Riomet only: 10 years of age or older

Diagnosis

Patient must have the following:

Diabetes mellitus Type 2

AND ONE of the following for Glumetza and Fortamet only:

1. Inadequate response
   a. Submission of medical records (e.g. chart notes, laboratory values) documenting a history of a minimum of 3 month trial with each of the following:
i. Immediate release metformin
ii. Extended-release metformin (generic Glucophage XR)

b. Patient must have a HgbA1C greater than 7.0%

2. Intolerance
   a. Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction) with a history of minimum of 3 month trial with each of the following:
      i. Immediate release metformin
      ii. Extended-release metformin (generic Glucophage XR)

**Riomet only:**

1. Documentation that the patient is unable to swallow or has difficulty swallowing metformin tablets
2. Patient must have a HgbA1C greater than 7.0%

AND documentation of the following for ALL formulations:
1. Serum creatinine levels < 1.5 mg/dL for men, < 1.4 mg/dL for women or normal creatinine clearance
2. **NO** hepatic impairment
3. **NO** metabolic acidosis, including diabetic ketoacidosis

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

**Prior – Approval Renewal Requirements**

**Age**
- **Glumetza and Fortamet only:** 18 years of age or older
- **Riomet only:** 10 years of age or older

**Diagnosis**

Patient must have the following:

- Diabetes mellitus Type 2
AND documentation of ALL of the following:

1. Submission of medical records (e.g. chart notes, laboratory values) documenting a reduction of A1c to ≤ 7.0%
2. Serum creatinine levels < 1.5 mg/dL for men, < 1.4 mg/dL for women or normal creatinine clearance
3. NO hepatic impairment
4. NO metabolic acidosis, including diabetic ketoacidosis

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Quantity**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Glumetza 500 mg</td>
<td>360 tablets per 90 days OR</td>
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<tr>
<td>Glumetza 1000 mg</td>
<td>180 tablets per 90 days</td>
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*Maximum daily limit of any Glumetza combination: 2000mg*

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<tr>
<th>Medication</th>
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<tbody>
<tr>
<td>Fortamet 500 mg</td>
<td>360 tablets per 90 days OR</td>
</tr>
<tr>
<td>Fortamet 1000 mg</td>
<td>180 tablets per 90 days</td>
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*Maximum daily limit of any Fortamet combination: 2500mg*

<table>
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<tr>
<th>Medication</th>
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<tbody>
<tr>
<td>Riomet 500 mg/5 mL</td>
<td>2365 mL per 90 days</td>
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**Duration**
12 months

**Prior – Approval Renewal Limits**
Same as above
Rationale

Summary
Metformin is indicated to improve glycemic control in adult patients with type 2 diabetes mellitus. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, and loss of limbs. Proper control of diabetes may also lessen the risk of a heart attack or stroke. Metformin works by helping to restore the body's proper response to the insulin it naturally produces. It also decreases the amount of sugar that the liver makes and that the stomach/intestines absorb. The safety and effectiveness of Glumetza and Fortamet in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Riomet in pediatric patients less than 10 years of age have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Metformin while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action Description</th>
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<tbody>
<tr>
<td>October 2015</td>
<td>Addition to PA</td>
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<tr>
<td>December 2015</td>
<td>Annual review</td>
</tr>
<tr>
<td>February 2016</td>
<td>Addition of inadequate response, intolerance to all of the following: generic form of Glumetza, generic form of Glucophage ER. Also addition of the requirement of inadequate response, intolerance to the generic form of Glumetza in the renewal section</td>
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<tr>
<td>March 2016</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td></td>
<td>Policy number change from 5.07.20 to 5.30.20</td>
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<tr>
<td>June 2016</td>
<td>Addition of Managed PA documentation and generic Glumetza</td>
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<tr>
<td>September 2016</td>
<td>Annual review and reference update</td>
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<tr>
<td>July 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>December 2018</td>
<td>Removal of Brand Glumetza</td>
</tr>
<tr>
<td>March 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>February 2019</td>
<td>Addition of statement: *Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.</td>
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<tr>
<td>March 2019</td>
<td>Annual review. Merged with Policy 5.30.50 Fortamet Riomet and renamed</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.

policy Metformin. Increased Fortamet age requirement to 18 and older and added A1c requirements to Riomet