

Drug Policy

Policy:	Riomet (metformin oral solution) Riomet ER (metformin oral suspension)	Annual Review Date: 02/20/2024 Last Revised Date: 02/20/2024
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OVERVIEW

Riomet (metformin hydrochloride oral solution) and Riomet ER (metformin hydrochloride oral suspension) are indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 2 diabetes mellitus.

Dosage of Riomet must be individualized based on both effectiveness and tolerance. The maximum recommended daily dose of Riomet is 2550 mg (25.5 mL) in adults and 2000 mg (20 mL) in pediatric patients (10 to 16 years of age per prescribing information). Riomet should be given in divided doses with meals. Riomet should be started at a low dose with gradual dose escalation, both to reduce gastrointestinal side effects and to permit monitoring of glycemic control of the patient.

POLICY STATEMENT

This policy involves the use of Riomet. Prior authorization is recommended for pharmacy benefit coverage of Riomet. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Riomet is recommended in those who meet the following criteria:

1. Diabetes Mellitus, Type 2

Criteria. *Patient must meet the following criteria*

- A. The patient is 10 years of age or older; AND
- B. The prescribed medication is being used as an adjunct to diet and exercise to improve glycemic control; AND
- C. The patient is unable to swallow the oral tablet dose forms due to the following (a OR b):
 - a. Dysphagia; OR
 - b. The individual is between 10 to 12 years of age; AND
- D. Riomet is not prescribed based on patient preference or convenience; AND
- E. If brand Riomet oral solution is requested, the patient has tried and failed generic metformin oral solution

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Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Riomet has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Riomet oral solution [prescribing information]. Jacksonville, FL: Sun Pharmaceutical Industries, Inc.; August 2019.
2. Metformin hydrochloride. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 8 February 2024. Accessed 20 February 2024.
3. Riomet ER [prescribing information]. Sun Pharmaceutical Industries, Inc. August 2019.