Orforglipron (FOUNDAYO) Oral Tablets for Weight Management
Criteria for Use
May 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive orforglipron (FOUNDAYO) for chronic weight management.

- ☐ Known pregnancy ^1
- ☐ Lactating ^2
- ☐ Type 1 diabetes ^3
- ☐ Personal or family history of medullary thyroid carcinoma or with Multiple Endocrine Neoplasia syndrome type 2
- ☐ Severe gastrointestinal dysmotility, including gastroparesis
- ☐ History of pancreatitis (does not pertain to patients for whom the cause of pancreatitis is known and no longer presents a risk) ^4
- ☐ Known PDR, severe NPDR, clinically significant ME, or DME unless risks/benefits have been discussed with the patient and documented in the EHR with monitoring plans and follow-up with an eye specialist who is informed at the time of the initiation ^5
- ☐ Severe hepatic impairment (Child-Pugh Class C)
- ☐ Concurrent therapy with a strong CYP3A4 inducer (e.g., carbamazepine, phenytoin, rifampin)^6
- ☐ Concurrent therapy with a strong CPY3A4 inhibitor that also inhibits OATP1B (e.g., ritonavir, clarithromycin)^6

DME=diabetic macular edema; EHR=electronic health record; ME=macular edema; NPDR=non-proliferative diabetic retinopathy; PDR=proliferative diabetic retinopathy

1. Weight loss offers no potential benefit to a pregnant female and may result in fetal harm; refer to product information
2. Breastfeeding women excluded from clinical trials for weight management; in general, weight management should focus on healthy nutrition, behavioral modification and exercise, as well as take into consideration the energy requirements for breastfeeding. Consider individual risk vs. benefit in the woman and the breastfed infant.
3. There is no evidence of increased risk for DKA with GLP-1/GIP use in type 1 diabetes. If the patient is followed by a diabetes/weight management specialist, orforglipron can be considered for weight management under careful supervision in patients with type 1 diabetes.
4. Risk factors for pancreatitis include triglyceride level > 1000 mg/dL, known gallstones with intact gallbladder, high alcohol intake
5. Rapid improvement in glucose control has been associated with temporary worsening of diabetic retinopathy. Orforglipron has not been studied in patients with NPDR requiring acute therapy, PDR, or DME. Before considering treatment with orforglipron in patients with diabetes, the provider should have the results of diabetic eye exam completed within past 12 months (or 24 months if no evidence of retinopathy). Decision to use orforglipron should consider disease severity and activity. Patients with a history of diabetic retinopathy should have planned follow-up with the eye provider to monitor progression. Consultation with an eye care specialist should be obtained any time there are concerns related to use in patients with diabetic retinopathy.
6. Orforglipron has dosing limits/recommendations for other oral medications (e.g., simvastatin) and moderate CYP3A4 inhibitors and inducers, see Prescribing Information for details.

Inclusion Criteria

The answer to the following must be fulfilled in order to meet criteria for orforglipron (FOUNDAYO) for chronic weight management.

- ☐ Documented participation in a comprehensive lifestyle intervention (CLI) that targets all three aspects of weight management: diet, physical activity, behavioral changes ^7
- ☐ BMI is greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity ^8 ^9

7. Participation in a CLI is an essential component to overall weight management. Veterans who have documentation of CLI participation within the past year on at least one occasion/visit are eligible for consideration of a weight management medication. The MOVE! program is one example of CLI provided in VA. Other methods can also be considered in coordination with the National Center for Healthcare Promotion's required elements: https://dvagov.sharepoint.com/sites/vhamove/Shared%20Documents/NCP-MOVE-CLI-Definition.pdf
8. BMI = Body Mass Index; Examples of weight-related comorbidities include but are not limited to: hypertension, type 2 diabetes, prediabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, metabolic dysfunction-associated steatotic liver disease, heart failure with preserved ejection fraction, previous myocardial infarction, previous stroke, or symptomatic peripheral arterial disease (defined as: intermittent claudication with ankle–brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease).
9. If clinically appropriate, consider discontinuing medications that may precipitate weight gain. Refer to the Sidebar on Select Medications and their Potential Effects on Weight in the VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity at: https://www.healthquality.va.gov/guidelines/CD/obesity/index.asp

Additional Inclusion Criteria *(Select if applicable)*

- ☐ For females who can become pregnant: Pregnancy should be excluded prior to receiving orforglipron and there should be contraceptive counseling on potential risks vs. benefits of taking orforglipron if she were to become pregnant
- ☐ Females of childbearing potential who are using oral contraceptives have been counseled to switch to a non-oral contraceptive method or add a barrier method of contraception for 30 days after initiation and for 30 days after each dose escalation

Supplemental Information

Orforglipron can be taken with or without food. Refer to PBM-MAP-VPE Clinical Guidance: Weight Management Medications for Chronic Use Clinical Recommendations for Treatment Selection at: PBM Formulary Management - Clinical Recommendations - All Documents (sharepoint.com) or https://www.va.gov/formularyadvisor/

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