IOWA Health and Human Services

# Request for Prior Authorization Incretin Mimetics for Non-Diabetes Indications

**FAX Completed Form To**
1 (800) 574-2515
**Provider Help Desk**
1 (877) 776-1567

(PLEASE PRINT – ACCURACY IS IMPORTANT)

| IA Medicaid Member ID # | Patient name | DOB |
|---|---|---|
| Patient address | | |
| Provider NPI | Prescriber name | Phone |
| Prescriber address | | Fax |
| Pharmacy name | Address | Phone |

**Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.**

| Pharmacy NPI | Pharmacy fax | NDC |
|---|---|---|

Prior authorization (PA) is required for incretin mimetics not otherwise covered by the Anti-Diabetics Non-Insulin Agents PA criteria for covered FDA approved for compendia indications. Payment for excluded medical use(s) (e.g. weight loss), as defined in the Iowa State Plan and Iowa Administrative Code 441 – 78.2(4) will be denied. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including dosing, contraindications, warning and precautions, drug interactions, and use in specific populations; and
2. Patient has been screened for and does not have type 1 or type 2 diabetes mellitus; and
3. The requested drug will be used to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in an adult with established cardiovascular disease (CVD) and either obesity or overweight; and
    a. Patient has established CVD, i.e. coronary artery disease (angina, MI), cerebrovascular disease (stroke, transient ischemic attack), peripheral arterial disease, heart failure, atrial fibrillation and other arrhythmias, valvular heart disease, congenital heart disease, cardiomyopathies, aortic disease (aneurysm, dissection), DVT or PE, and
    b. Patient has a baseline body mass index (BMI) ≥ 27kg/m$^2$, obtained within 6 months of request; and
    c. Patient has been evaluated for cardiovascular standard of care treatment; and
    d. For Wegovy:
        i. Patient is ≥ 18 years of age; and
        ii. Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and
        iii. Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment; or
4. Patient has a diagnosis of moderate to severe obstructive sleep apnea (OSA); and
    a. Patient has a baseline BMI ≥ 30kg/m$^2$; and
    b. Prescriber attests patient has a recent (within prior three years) apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a polysomnography (PSG) or at-home sleep study (document AHI); and
    c. For Zepbound:
        i. Patient meets the FDA approved age for OSA; and
        ii. Initiation and escalation dosages will be permitted up to a maximum of 20 weeks prior to reaching the recommended maintenance dosage of 10 mg to 15 mg once weekly; and
        iii. Maintenance dosages other than 10 mg to 15 mg once weekly will not be approved for maintenance treatment; or
5. Patient has a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH); and

a. Patient has moderate to advanced liver fibrosis (stages F2 to F3 fibrosis) as confirmed by one of the following (attach results from testing documenting fibrosis stage);
    i. Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g. FibroScan), with a LSM of 8kPa to 15 kPa; or
    ii. LSM by magnetic resonance elastography (MRE) with a LSM or 3.1 kPa to 4.4 kPa; or
    iii. Liver biopsy with a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) ≥4 with a score of 1 or more in steatosis, lobular inflammation, and hepatocyte ballooning; and
b. Patient has been evaluated for cardiometabolic standard of care treatment; and
c. Concurrent use of an incretin mimetic with resmetirom (Rezdiffra) for the treatment of MASH will only be considered after documented trials of each agent individually at therapeutic doses, with evidence of inadequate response; and
d. Patient has not had significant alcohol consumption within the past year (> 20 g per day in women or > 30 g per day in men); and
e. For Wegovy:
    i. Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and
    ii. Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment (see requests for continuation of therapy below for maintenance dose requirement); and

6. Patient will use medication in combination with a reduced calorie diet and increased physical activity; and
7. The requested agent will not be used in combination with other incretin mimetics.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Requests will be considered for initiation and appropriate dosage escalation. Requests for continuation of therapy, once at an established maintenance dose, will be considered when:

1. The requested drug will be used to reduce the risk of MACE; and
    a. Patient has been evaluated for cardiovascular standard of care treatment; and
    b. For Wegovy, a maintenance dose of 1.7 mg or 2.4 mg weekly is requested; or
2. The requested drug will be used to treat moderate to severe OSA; and
    a. Documentation of a positive response to therapy is provided; and
    b. The maintenance dose is requested and maintained (Zepbound 10 mg to 15 mg once weekly); or
3. The requested drug will be used for noncirrhotic MASH; and
    a. Documentation of a positive response to therapy (e.g., improvement in or stabilization of fibrosis, improvement in liver function such as reduction in alanine aminotransferase [ALT], improvement in LSM by VCTE, MRE, or biopsy); and
    b. Patient has not progressed to cirrhosis; and
    c. For Wegovy, a maintenance dose of 2.4 mg once weekly is requested, or 1.7 mg weekly with documentation of an adequate trial and intolerance to the maintenance dose of 2.4 mg once weekly. Patient must have a retrial of the recommended maintenance dose of 2.4 mg once weekly at least annually before a maintenance dose of 1.7 mg will be reauthorized; and

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4. Patient does not have type 1 or type 2 diabetes; and
5. Patient continues to use medication in combination with a reduced calorie diet and increased physical activity; and
6. The requested agent will not be used in combination with other incretin mimetics.

**Preferred**

☐ Zepbound ☐ Wegovy

| Strength | Usage Instructions | Quantity | Day's Supply |
|---|---|---|---|
| _____ | _____ | _____ | _____ |

Diagnosis: _____

**Initial Requests:**

**Does patient have Type 1 or Type 2 Diabetes?** ☐ Yes ☐ No

**Will patient be using medication in combination with a reduced calorie diet and increased physical activity?** ☐ Yes ☐ No

**Will the requested agent be used in combination with other incretin mimetics?** ☐ Yes ☐ No

**Requests for MACE:**

**Patient has established CVD:**

- ☐ Coronary Artery Disease
- ☐ Cerebrovascular Disease
- ☐ Peripheral Arterial Disease
- ☐ Heart Failure
- ☐ Atrial Fibrillation and other arrhythmias
- ☐ Valvular Heart Disease
- ☐ Congenital Heart Disease
- ☐ Cardiomyopathies
- ☐ Aortic Disease
- ☐ DVT or PE

**Provide patient's baseline BMI:** _____ Date Obtained: _____

**Has patient been evaluated for cardiovascular standard of care treatment?** ☐ Yes ☐ No

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**Requests for MASH:**

**Attach testing results documenting moderate to advanced liver fibrosis (stages F2 to F3 fibrosis)**

**Has patient been evaluated for cardiometabolic standard of care treatment?** ☐ Yes ☐ No

**Will incretin mimetic be used concurrently with Rezdiffra?**

☐ Yes: Document trials of each agent individually at therapeutic doses:
_____

☐ No

**Has patient had significant alcohol consumption within the past year (> 20 g per day in women and > 30 g per day in men)?** ☐ Yes ☐ No

**Requests for OSA:**

**Provide patient's baseline BMI:** _____ Date Obtained: _____

**Does patient have a recent (within prior three years) apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a PSG or at-home sleep study?**
☐ Yes Document AHI: _____ ☐ No

**Renewal Requests:**

**Does patient have Type 1 or Type 2 Diabetes (attach lab results documenting current A1C or fasting plasma glucose)?** ☐ Yes ☐ No

**Patient continues to use medication in combination with a reduced calorie diet and increased physical activity?** ☐ Yes ☐ No

**Will the requested agent be used in combination with other incretin mimetics?** ☐ Yes ☐ No

**MACE:**

**Has patient been evaluated for cardiovascular standard of care treatment?** ☐ Yes ☐ No

**MASH:**

**Document positive response to therapy:** _____
_____

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**Has patient progressed to cirrhosis?** ☐ Yes ☐ No

**For doses other than 2.4 mg once weekly, document date of last trial of 2.4mg once weekly: _____**

**OSA:**

**Document positive response to therapy: _____**
**_____**

***Attach lab results and other documentation as necessary.***

| Prescriber signature (Must match prescriber listed above.) | Date of submission |
|---|---|
| | |

***IMPORTANT NOTE:*** *In evaluating requests for prior authorization, the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary, by contact with the county Department of Health and Human Services, that the member continues to be eligible for Medicaid.*