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Our reference
2022044863

Date 23 November 2022
Subject Request for advice List 2 conditions Saxenda® and Mysimba®

Dear Mr Kuipers,

In your letter of 22 October 2022 (reference 3441557-1035630-GMT), you request an assessment of whether any adjustments are required for the current List 2 conditions of liraglutide (Saxenda®) and naltrexone/bupropion (Mysimba®).

Reason for request
Your request is based on the communications, at an office level, between the Ministry and the National Health Care Institute. These communications have indicated a possible lack of clarity, in the practical field, about the List 2 conditions for these medicinal products, with regards to the appropriateness agreements already made by the occupational group. Adaptation of the List 2 conditions could possibly eliminate this ambiguity.

Considerations
Current reimbursement conditions
As of 1 April 2022, the following List 2 condition will be applied for the reimbursement of liraglutide (Saxenda®) for a subgroup of patients:

Condition
in combination with a combined lifestyle intervention (CLI) recognized by the RIVM, for the treatment of adults with an extremely increased weight-related health risk, without type 2 diabetes and who are not (yet) eligible for metabolic surgery:
- BMI ≥35 kg/m2 in combination with a co-morbidity (cardiovascular disease, sleep apnoea and/or osteoarthritis) or
- A BMI ≥40 kg/m2

Treatment should be discontinued if after 3 months of using the maintenance dosage the initial weight has not decreased by at least 5%.

As of 1 August 2022, you have also admitted the combination preparation naltrexone/bupropion (Mysimba®) to the basic health care package under the following List 2 condition:

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Condition
In combination with a combined lifestyle intervention (CLI) recognized by the RIVM, for the treatment of adults with:
- BMI ≥30 kg/m2 or
- BMI 27 kg/m2 to 30 kg/m2 in combination with a comorbidity ((risk factors) for cardiovascular disease, type 2 diabetes, sleep apnoea and/or osteoarthritis).

Treatment should be discontinued if, after 4 months of use, the initial weight has not decreased by at least 5%.

Occupational group appropriateness agreements
After the above-mentioned medicinal products were included in the basic health care package, the occupational group took the initiative to set up a number of appropriateness agreements and to communicate them to the field using a Q&A. This is partly in response to the questions from the field about the reimbursement of these products. These appropriateness agreements are in line with the current Standard of care for obesity (2010).

One of these agreements relates to the clarification of the start criteria for the use of liraglutide and naltrexone/bupropion. The use of these products can only be considered if, after one year of treatment, the CLI is unsuccessful:
- <5% weight loss – with moderately increased weight-related health risk (GGR)
- <10% weight loss – with a significantly increased weight-related health risk (GGR)

Advice
To remove the uncertainty in the field regarding the List 2 condition in relation to the appropriateness agreements made by the occupational group, we advise you to adjust the List 2 condition for liraglutide and naltrexone/bupropion as follows in order to promote appropriate care (bold print):

Liraglutide condition (Saxenda®)
In combination with a combined lifestyle intervention (CLI) recognized by the RIVM, **if the CLI is unsuccessful after one year**, for the treatment of adults with an extremely increased weight-related health risk, without type 2 diabetes and who are not (yet) eligible for metabolic surgery:
- BMI ≥35 kg/m2 in combination with a co-morbidity (cardiovascular disease, sleep apnoea and/or osteoarthritis) or
- A BMI ≥40 kg/m2

Treatment should be discontinued if after 3 months of using the maintenance dosage the initial weight has not decreased by at least 5%.

Naltrexone/bupropion condition (Mysimba®)
In combination with a combined lifestyle intervention (CLI) recognized by the RIVM, **if the CLI is unsuccessful after one year**, for the treatment of adults with:
- BMI ≥30 kg/m2 or
- BMI 27 kg/m2 to 30 kg/m2 in combination with a comorbidity ((risk factors) for cardiovascular disease, type 2 diabetes, sleep apnoea and/or osteoarthritis).

Treatment should be discontinued if, after 4 months of use, the initial weight has not decreased by at least 5%.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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